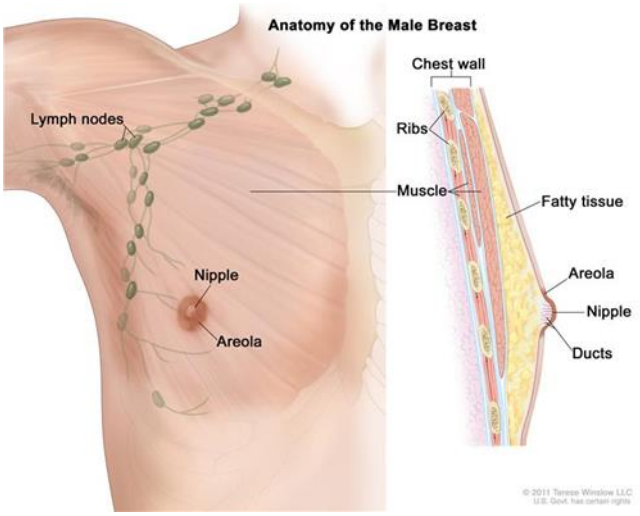
Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet on Breast Cancer in Men

Introduction

The exterior of all humans' chests are basically the same. However, the size, shape, and function of breasts vary significantly between the sexes.



[Picture Credit: Male Breast]

Like its female counterpart, the male breast has a nipple and an areola (the darker pigmented circle around the nipple), but men lack the mammary glands and ducts necessary to produce milk.

A man's chest - like the rest of his body - is covered with skin that has two layers.

- The epidermis is the outermost layer that provides a protective, waterproof seal over the body.
- The dermis is the under layer that contains sweat glands, hair follicles, blood vessels, and more.

Unlike a woman's chest, the male chest typically develops some type of thick, dark hair in late puberty that usually does not reach full growth until the early 30s. Like a woman's breasts, men's chest hair is a secondary sex characteristic, or a feature that distinguishes the differences between the two sexes.

Despite what some men have been told, black coffee, burnt toast, beer, and other substances will not give men chest hair or make it curl more. Chest hair growth depends on genetics, age, and hormonal status.

Unlike women, a typical male does not have extensive fat deposits on his chest - in a woman, these protect the mammary glands. Instead, the shape of a man's chest is determined by the muscles underneath the skin.

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Although atypical, men can develop large mammary glands that result in breast enlargement. This condition is known as gynaecomastia. It is more common is adolescent boys but typically disappears after puberty. The cause of gynaecomastia is unknown in some people, but it may be caused by steroid abuse, drug interaction, obesity, and hormone imbalance. Treatment depends on the underlying cause.
(Healthline).

Incidence of Breast Cancer in Men in South Africa
According to the National Cancer Registry (2013) the following cases of Breast Cancer in Men was histologically diagnosed in 2013:

Group 2013	Actual Number of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	156	1 : 945	0,43%
Asian males	4	1 : 1 585	0,62%
Black males	102	1 : 933	0,50%
Coloured males	12	1 : 876	0,30%
White males	37	1 : 874	0,18%

Frequency of Histologically Diagnosed Cases of Breast Cancer in Men
According to the National Cancer Registry (2013), the frequency of histologically diagnosed cases of Breast Cancer in Men in South Africa is as follows:

Group 2013	0 to 19 Years	20 to 29 Years	30 to 39 Years	40 to 49 Years	50 to 59 Years	60 to 69 Years	70 to 79 Years	80 + Years
All males	0	2	8	24	37	42	29	7
Asian males	0	0	0	1	1	2	0	0
Black males	0	2	6	15	24	24	18	4
Coloured males	0	0	0	1	4	5	2	0
White males	0	0	1	7	7	9	9	2

Risk Factors for Breast Cancer in Men
Men diagnosed with male breast cancer at an early stage have a good chance for a cure. Still, many men delay seeing their doctors if they notice unusual signs or symptoms, such as a breast lump. For this reason, many male breast cancers are diagnosed when the disease is more advanced.

Factors that increase the risk of male breast cancer include:

- Older age. Breast cancer is most common in men ages 40 to 80. About 1 in 5 men with breast cancer (20%) have a close relative who has also had breast cancer. The genes store the biological information inherited from parents. The genes most commonly linked to an increased risk of breast cancer in families are BRCA1 and BRCA2. Men in families with the BRCA2 gene are more likely to develop breast cancer than men in BRCA1 families. It is thought that the BRCA2 gene may cause up to 1 in 10 of breast cancers in men (10%).

- Exposure to oestrogen. If one takes oestrogen-related drugs, such as those used as part of sex reassignment surgery, the risk of breast cancer is increased. Oestrogen drugs may also be used in hormone therapy for prostate cancer. Although all men have oestrogen in their bodies, obesity, cirrhosis (liver disease) and Klinefelter's syndrome (a genetic disorder) increase oestrogen levels.

- Family history of breast cancer. If one has a close family member with breast cancer, there is a greater chance of developing the disease. If a first-degree relative—their mother, father, brother, sister, children—has breast cancer, men are also at slightly higher risk to develop the disease themselves. Men who have a BRCA mutation (a mutation or change in a gene that predisposes them to breast cancer) are at a greater risk. Although their chance of developing breast cancer is still low (only about 5% to 6%), men with a mutation in BRCA2 have a 100-fold greater risk of developing breast cancer than men in the general population.

There may be a breast cancer gene in a family if:

- a man in the family has breast cancer
- there are three close relatives on the same side of the family who developed breast cancer at any age
- there are two close relatives on the same side of the family who developed breast cancer under the age of 50
- there is one close relative who developed breast cancer under the age of 40
- there is a close relative with breast cancer in both breasts
- there is a close relative with breast cancer and another relative on the same side of the family with ovarian cancer

Close relatives, sometimes called one's first degree relatives, are parents, children, sisters and brothers.

- Klinefelter's syndrome. This genetic syndrome occurs when a boy is born with more than one copy of the X chromosome. Klinefelter's syndrome causes abnormal development of the testicles. As a result, men with this syndrome produce lower levels of certain male hormones (androgens) and more female hormones (oestrogens).

- being a heavy user of alcohol, which can limit the liver's ability to regulate blood oestrogen levels.

- Liver disease. If one has liver disease, such as cirrhosis of the liver, the male hormones may be reduced and female hormones may be increased. This can increase the risk of breast cancer.

- Obesity. Obesity may be a risk factor for breast cancer in men because it increases the number of fat cells in the body. Fat cells convert androgens into oestrogen, which may increase the amount of oestrogen in the body and, therefore, the increased risk of breast cancer.

- Radiation exposure. If one has received radiation treatments to the chest, such as those used to treat cancers in the chest, one is more likely to develop breast cancer later in life.

(Mayo Clinic; MacMillan Cancer Support; Breastcancer.org; US Food and Drug Administration).

Symptoms and Signs of Breast Cancer in Men

Symptoms of breast cancer in men are similar to those in women. Most male breast cancers are diagnosed when a man discovers a lump on his breast. But unlike women, men tend to delay going to the doctor until they have more severe symptoms, like bleeding from the nipple. At that point the cancer may have already spread.

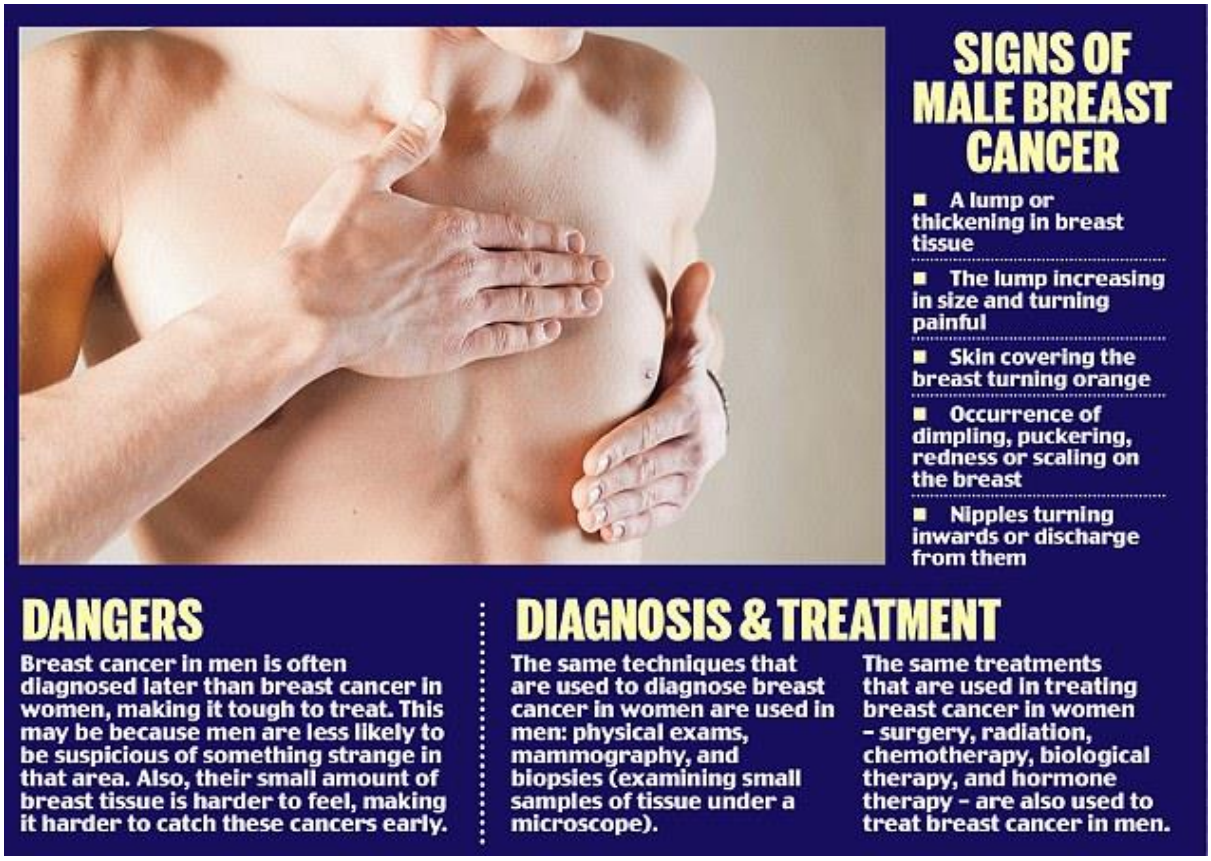
The most common sign of breast cancer in men is a firm, non-painful mass located just below the nipple. There may not be other associated symptoms. The average size of breast cancer in men when first discovered is about 2.5 cm in diameter.

The cancer may cause skin changes in the area of the nipple. These changes can include:

- ulceration of the skin
- puckering or dimpling
- redness or scaling of the nipple
- retraction (turning inward) of the nipple
- bloody or opaque discharge from the nipple may also occur

Less than 1% of cases are bilateral (occurring on both sides).

Breast cancer that has spread (metastasised) to the bones may also produce bone pain at the sites of metastases. Advanced breast cancer can also produce symptoms typical of many cancers, including malaise, weakness, and weight loss. Breast cancer in men can spread to many other organs and cause other symptoms as well.



[Picture Credit: Male Breast Cancer]

It is important to note that enlargement of both breasts (not just on one side) is usually NOT cancer. The medical term for this is gynaecomastia. Sometimes the breasts can become quite large. Non-cancer-related enlargement of the breasts can be caused by medications, heavy alcohol use, weight gain, or marijuana use.
(WebMD; MedicineNet.com; Breastcancer.org).

Diagnostic Tests for Early-Stage Breast Cancer
According to the South African National Cancer Registry (2011) 7 086 women and 149 men were diagnosed with breast cancer. If one is diagnosed with breast cancer, it is important that doctors get as much information as they can about the tumour so they can make the best recommendations to treat the cancer.

This section provides an overview of the general diagnostic tests that help doctors understand a patient's tumour type. It also describes newer tests that offer additional information for women with certain types of early-stage (stage I or II) breast cancer.

Understanding one's tumour type - tests performed on tumour samples give valuable information that helps guide treatment decisions for breast cancer. By examining tumour samples under a microscope, doctors can determine if the tumour is invasive or noninvasive (in situ).

The tumour sample will also help identify the tumour's grade -whether it is a fast-growing or slow-growing form of breast cancer - as well as the tumour's hormone receptor status and HER2 status. All of these tests will inform the oncologist about a recommended treatment plan.

Sentinel node mapping also helps doctors determine if breast cancer cells have spread to other parts of the body. If the sentinel (first) lymph node is cancer free, the nearby lymph nodes may also be unaffected and left intact. Removing a patient's lymph nodes can affect her/his quality of life because it increases her/his risk of lymphoedema, a painful swelling of the arm.

Determining hormone status - oestrogen and progesterone receptors are structures present on the surface of some cancer cells. These structures allow oestrogen and progesterone to enter the cells and encourage them to grow.

Tumours that test positive for these structures are called hormone receptor-positive and might be successfully treated with hormonal therapy (e.g., tamoxifen or aromatase inhibitors). These treatments prevent oestrogen from attaching to receptors on breast cancer cells.

As a result, oestrogen cannot get in the cells, and tumour growth is slowed. The treatments also reduce the amount of hormones circulating in the body that attach to oestrogen or progesterone receptors. By blocking hormones, the treatments deprive tumour cells of the substances they need to grow.

HER2-positive breast cancers are breast tumours that make too much of a substance called HER2/neu, which speeds the growth of cancer cells. About 20 percent of breast cancers are HER2-positive. Drugs that target HER2/neu slow the growth of the tumour.
Such drugs include trastuzumab (Herceptin) and lapatinib (Tykerb). The breast cancer will be tested to identify if it is HER2-positive to determine the best treatment options.

Triple-negative breast tumours do not depend on oestrogen, progesterone, or HER2 for their growth, and account for about 15 percent of all breast cancers. The standard treatments include surgery, radiation and chemotherapy.

Researchers are looking for new ways to combine chemotherapy and targeted drugs to offer the most benefit to those living with triple-negative breast cancer.

Personalising breast cancer treatment - some of the newest tools for women with breast cancer are tests that estimate the likelihood of deriving a benefit from chemotherapy. Currently, there are two tests approved for estimating a patient's risk of recurrence with early-stage breast cancer: Onco*type* DX and MammaPrint.

Onco*type* DX and MammaPrint are appropriate for women with stage I or II breast cancer that is hormone receptor-positive and will be receiving hormonal therapy. For those who are “on the fence” about embarking on a course of chemotherapy, these tests may provide sufficient information to make the decision clearer and easier. Both tests work by analyzing the genes in tumour tissue removed during surgery.

The tests look for patterns of abnormal genetic activity to predict how the tumour will behave. Oncotype DX examines the activity of 21 genes to determine chance of recurrence, and MammaPrint looks at 70 different genes.

The National Cancer Institute is using Onco*type* DX in a clinical trial called TAILORx to study recently diagnosed patients with hormone receptor-positive, HER2-negative breast cancer that has not spread to the lymph nodes.

The TAILORx study is just one example of how research is transforming the way that doctors treat breast cancer - that is, basing their treatment approach on the patient's tumour. If doctors know in advance that a treatment will not be of benefit, the patient could be spared unnecessary side effects from the treatment.
(Cancer Therapy Advisor)

Diagnosis of Breast Cancer in Men

- The same techniques that are used to diagnose breast cancer in women are used in men: physical examinations
- Mammography
- biopsies (examining small samples of tissue under a microscope)

[Picture Credit: Male Mammography]

Genetic Counselling Is a Must for Men
All men with breast cancer should be referred for genetic counselling.

This is different from women who are not automatically referred to a genetic counsellor for genetic testing, such as for mutations in BRCA-1 or 2. These “tumour suppressor genes” allow breast and other types of cancer to develop when they fail to function normally. Only women with a significant family history or certain other characteristics, such as being young or having triple-negative breast cancer (which lacks oestrogen, progesterone, and HER2 receptors), are recommended to have genetic testing.

Even among men there are differences. African American men are more likely than white men to have advanced stage tumours at diagnosis and to develop triple-negative cancers. Their types of tumours are more likely to recur and have fewer treatment options.

People should tell their health care provider if any man in their family has had breast cancer. Even if one’s grandfather is deceased, if he had breast cancer, that is important. Because male breast cancer is so rare, seeing even one man in a family lineage raises concerns about hereditary breast cancer.
(US Food and Drug Administration).

Types of Breast Cancer in Men

The most common type of male breast cancer is infiltrating ductal carcinoma, which is also a common type of breast cancer in women. Ductal carcinoma refers to cancers with origins in the ducts (tubular structures) of the breast, and the term infiltrating means that the cancer cells have spread beyond the ducts into the surrounding tissue. On the other hand, lobular cancers (cancers of the milk glands), common in women, are extremely rare in men since male breast tissue does not normally contain lobules.

Other uncommon types of cancers of the breast that have been reported in men include ductal carcinoma in situ (cancer in the ducts that has not spread beyond the ducts themselves), cystosarcoma phyllodes (a type of cancer of the connective tissue surrounding the ducts), and Paget's Disease of the breast (a cancer involving the skin of the nipple). Some other types of breast cancer that occur in men are named for their growth patterns and microscopic appearance of the cancer cells, including papillary carcinoma, inflammatory carcinoma, and medullary carcinoma.

About 85% of breast cancers in men have oestrogen receptors on their cell membranes. Oestrogen receptors on the cell membranes allow oestrogen molecules to bind to the cancer cells. Oestrogen binding to the cancer cells can stimulate cell growth and multiplication.
(MedicineNet.com;

Special Tests
The following tests and investigations may be ordered:

Breast ultrasound - ultrasound, also known as *sonography*, uses high-frequency sound waves to outline a part of the body. Most often for this test, a small, microphone-like instrument called a *transducer* is placed on the skin (which is first lubricated with gel). It emits sound waves and picks up the echoes as they bounce off body tissues. The echoes are converted by a computer into a black and white image on a computer screen. A newer ultrasound machine that was designed to look at the breast uses a much larger transducer that can examine the entire breast at once.
This test is painless and does not expose one to radiation.

Breast ultrasound is sometimes used to evaluate breast abnormalities that are found during a physical examination. It can be useful to see if a breast lump or mass is a cyst or a tumour. A cyst is a non-cancerous, fluid-filled sac that can feel the same as a tumour on a physical examination. A mass that is not a simple cyst will often need to be biopsied.

Magnetic resonance imaging (MRI) of the breast - MRI scans use radio waves and strong magnets instead of X-rays. The energy from the radio waves is absorbed and then released in a pattern formed by the type of body tissue and by certain diseases. A computer translates the pattern into a very detailed image of parts of the body. For breast MRI to look for cancer, a contrast liquid called *gadolinium* is injected into a vein before or during the scan to show details better.

MRI scans can take a long time - often up to an hour. The patient has to lie inside a narrow tube. The platform contains the sensors needed to capture the MRI image. It is important to remain very still throughout the exam. Lying in the tube can feel confining and might upset people with claustrophobia (a fear of enclosed spaces). The machine also makes loud

buzzing and clicking noises that one may find disturbing. Some places will give the patient headphones with music to block this noise out. MRIs are expensive.

MRI is also sometimes used in someone who has been diagnosed with breast cancer to better determine the actual size of the cancer and to look for any other cancers in the breast.

Nipple discharge examination - fluid leaking from the nipple is called *nipple discharge*. If a patient has a nipple discharge, he should have it checked by his doctor. If there is blood in this fluid, the patient might need more tests. One test collects some of the fluid to look at under a microscope to see if cancer cells are present. This test is often not helpful, since a breast cancer can still be there even when no cancer cells are found in the nipple discharge. Other tests may be more helpful, such as a breast ultrasound. If a man has a breast mass, he will probably need a biopsy (even if the nipple discharge does not contain cancer cells or blood).

Biopsy - a biopsy removes a body tissue sample to be looked at under a microscope. A biopsy is the only way to tell if a breast abnormality is cancerous. Unless the doctor is sure the lump is not cancer, this should always be done. There are several types of biopsies. Your doctor will choose the type of biopsy based on your situation.

- Fine needle aspiration biopsy: Fine needle aspiration (FNA) biopsy is the easiest and quickest biopsy technique. The doctor uses a very thin, hollow needle attached to a syringe to withdraw (aspirate) a small amount of tissue from a suspicious area. The doctor can guide the needle into the area of the breast abnormality while feeling the lump. A local anaesthetic (numbing medicine) may or may not be used. Because such a thin needle is used for the biopsy, the process of getting the anaesthetic might actually be more uncomfortable than the biopsy itself.

An FNA biopsy is the easiest type of biopsy to have, but it has some disadvantages. It can sometimes miss a cancer if the needle is not placed among the cancer cells. And even if cancer cells are found, it is usually not possible to determine if the cancer is invasive. In some cases there may not be enough cells to perform some of the other lab tests that are routinely done on breast cancer specimens. If the FNA biopsy does not provide a clear diagnosis, or your doctor is still suspicious, a second biopsy or a different type of biopsy should be done.

- Core needle biopsy: For a core biopsy, the doctor removes a small cylinder of tissue from a breast abnormality to be looked at under a microscope. The needle used in this technique is larger than that used for FNA. The biopsy is done with local anaesthesia and can be done in a clinic or doctor's office.

A core biopsy can be used to sample breast changes the doctor can feel, but it is also used to take samples from areas pinpointed by ultrasound or a mammogram. (When mammograms taken from different angles are used to pinpoint the biopsy site, this is known as a *stereotactic core needle biopsy*.) In some centres, the biopsy can be guided by an MRI scan.

Because it removes larger pieces of tissue, a core needle biopsy is more likely than an FNA to provide a clear diagnosis, although it might still miss some cancers.

- Surgical (open) biopsy: Most breast cancer can be diagnosed with a needle biopsy. Rarely, though, surgery is needed to remove all or part of the lump to know for certain if cancer is present. Most often, the surgeon removes the entire mass or abnormal area, as well as a surrounding margin of normal-appearing breast tissue. This is called an *excisional biopsy.* If the mass is too large to be removed easily, only part of it may be removed. This is called an *incisional biopsy*.

In rare cases, a surgical biopsy can be done in the doctor's office, but it is more commonly done in the hospital's outpatient department under local anaesthesia (you are awake, but the area around the breast is numb), often with intravenous sedation (medicine given into a vein to make you drowsy).

A surgical biopsy is more involved than an FNA biopsy or a core needle biopsy, and it often requires several stitches and may leave a scar. Sometimes, though, this type of biopsy is needed to get an accurate diagnosis.

All biopsies can cause bleeding and can lead to swelling. This can make it seem like the breast (or the lump in the breast) is larger after the biopsy. This is generally nothing to worry about and the bleeding and bruising go away quickly in most cases.

- Lymph node biopsy: Cancer in the breast can spread to lymph nodes under the arm and around the collar bone (clavicle). If any of these lymph nodes are enlarged, they may be biopsied. Often, a needle biopsy is done at the same time as the breast tumour is biopsied.

- Lymph node dissection and sentinel lymph node biopsy: These procedures are done specifically to look for breast cancer spread to lymph nodes.

(American Cancer Society).

Grading and Staging of Breast Cancer in Men

The following stages are used for male breast cancer:

The breast cancer stage is based on the results of testing that is done on the tumour and lymph nodes removed during surgery and other tests.

Stage 0 (carcinoma *in situ*). There are 3 types of breast carcinoma in situ:

- Ductal carcinoma in situ (DCIS) is a non-invasive condition in which abnormal cells are found in the lining of a breast duct. The abnormal cells have not spread outside the duct to other tissues in the breast. In some cases, DCIS may become invasive cancer and spread to other tissues. At this time, there is no way to know which lesions could become invasive.
- Paget's Disease of the nipple is a condition in which abnormal cells are found in the nipple only.
- Lobular carcinoma in situ (LCIS) is a condition in which abnormal cells are found In the lobules of the breast. This condition has not been seen in men.

Stage I

In Stage I, cancer has formed. Stage I is divided into stages IA and IB.

- In Stage IA, the tumour is 2 centimetres or smaller. Cancer has not spread outside the breast.
- In Stage IB, small clusters of breast cancer cells (larger than 0.2 millimetre but not larger than 2 millimetres) are found in the lymph nodes and either:
    - no tumour is found in the breast; or
    - the tumour is 2 centimetres or smaller.

Stage II

Stage II is divided into stages IIA and IIB.

In Stage IIA

- no tumour is found in the breast or the tumour is 2 centimetres or smaller. Cancer (larger than 2 millimetres) is found in 1 to 3 axillary lymph nodes or in the lymph nodes near the breastbone (found during a sentinel lymph node biopsy); or
- the tumour is larger than 2 centimetres but not larger than 5 centimetres. Cancer has not spread to the lymph nodes.

In Stage IIB, the tumour is:

- larger than 2 centimetres but not larger than 5 centimetres. Small clusters of breast cancer cells (larger than 0.2 millimetre but not larger than 2 millimetres) are found in the lymph nodes; or
- larger than 2 centimetres but not larger than 5 centimetres. Cancer has spread to 1 to 3 axillary lymph nodes or to the lymph nodes near the breastbone (found during a sentinel lymph node biopsy); or
- larger than 5 centimetres. Cancer has not spread to the lymph nodes.

Stage IIIA

In Stage IIIA:

- no tumour is found in the breast or the tumour may be any size. Cancer is found in 4 to 9 axillary lymph nodes or in the lymph nodes near the breastbone (found during imaging tests of a physical examination); or
- the tumour is larger than 5 centimetres. Small clusters of breast cancer cells (larger than 0.2 millimetre but not larger than 2 millimetres) are found in the lymph nodes; or
- the tumour is larger than 5 centimetres. Cancer has spread to 1 to 3 axillary lymph nodes or to the lymph nodes near the breastbone (found during a sentinel lymph node biopsy).

Stage IIIB

In stage IIIB, the tumour may be any size and cancer has spread to the chest wall and/or to the skin of the breast and caused swelling or an ulcer. Also, cancer may have spread to :

- up to 9 axillary lymph nodes; or
- the lymph nodes near the breastbone.

Cancer that has spread to the skin of the breast may also be inflammatory breast cancer.

Stage IIIC

In Stage IIIC, no tumour is found in the breast or the tumour may be any size. Cancer may have spread to the skin of the breast and caused swelling or an ulcer and/or has spread to the chest wall. Also, cancer has spread to:

- 10 or more axillary lymph nodes; or
- lymph nodes above or below the collarbone; or
- axillary lymph nodes and lymph nodes near the breastbone.

Cancer that has spread to the skin of the breast may also be inflammatory breast cancer. For treatment, stage IIIC breast cancer is divided into operable and inoperable stage IIIC.

Stage IV

In Stage IV, cancer has spread to other organs of the body, most often the bones, lungs, liver, or brain.

Treatment Options for Breast Cancer in Men

The same treatments that are used in treating breast cancer in women are also used to treat breast cancer in men, namely:

[Picture Credit: Mastectomy]

Surgery - Surgery is usually the first treatment if the breast abnormality is found to be a cancer. Surgery helps get complete information about the cancer and it is a critical step in treatment. The most common surgery in men is called a modified radical mastectomy. This means that the nipple, areola (dark, round area around the nipple), and all of the breast tissue are removed. The muscles on the chest are left alone. Lymph nodes are also removed.

A lumpectomy (breast-conserving surgery) is not usually done because men's breasts are so small. By the time the tumour and the tissue around it have been removed, very little breast tissue is left.

A mastectomy requires general anaesthesia and usually a night or longer in the hospital.

The lymph nodes reveal information about outlook and it helps doctors determine the best types of treatment against the cancer. The lymph nodes act as filters for the body's lymphatic drainage system. That is why the lymph nodes are likely to 'catch' or filter out cancer cells that might be floating in the fluid that drains away from the cancerous area of the breast.

The surgeon will inject a blue dye and a radioactive substance (called a tracer) into the tumour or the skin over the tumour. The first lymph nodes that turn blue and pick up the tracer are called the sentinel (meaning 'first') lymph nodes. The lymph node or nodes are then removed and sent to the pathologist, who looks to see if it contains any cancer cells. If no cancer cells are found, then no additional lymph node surgery is done.

If cancer cells are found in the nodes, then more underarm lymph nodes usually need to be removed. This is called an axillary (the armpit area) lymph node dissection (removal). There are three levels of axillary lymph nodes:

- Level I is the lowest level, closest to the breast.
- Level II is under a main muscle that sweeps through the armpit (pectoralis major).
- Level III refers to the lymph nodes just above this muscle.

A standard axillary lymph node dissection removes the lymph nodes from levels I and II. If the lymph nodes feel or look abnormal before surgery, then the standard axillary lymph node removal is usually done. The surgeon may still use the dye, tracer, or both to make sure that all of the important lymph nodes are identified and removed.

A potential side effect of lymph node removal is lymphoedema of the arm. This is a build-up of lymph fluid in the soft tissues of the arm along with swelling (also called oedema). One can think of lymphedema as a plumbing problem: Veins and lymphatic channels are like pipes and drains that can handle the normal load of lymphatic fluid. If lymph nodes and channels are removed, there might not be enough pipes and drains to handle all the fluid and the arm swells.

Radiation therapy - Radiation therapy is a highly targeted, highly effective way to destroy cancer cells that may linger after surgery. This reduces the risk of recurrence (the cancer coming back).

Radiation is usually given after mastectomy in men with:

- large cancers (5cm or bigger)
- a positive margin of resection (when the cancer comes very close to or is at the edge of the breast tissue removed)
- a significant area of lymphatic or blood vessel involvement
- significant lymph node involvement (four or more positive nodes)

After mastectomy, radiation therapy is usually given 5 days a week for about 5-7 weeks.

Radiation can also be used for men with advanced (metastatic) disease to relieve symptoms or help avoid complications from specific areas of spread. For example, radiation can help relieve painful bone metastases, decrease the risk of breaking a bone that's been weakened by cancer, decrease bleeding from skin involvement, and reduce neurological symptoms if the cancer puts pressure on nerves or the spinal cord.

Chemotherapy - Chemotherapy refers to special medicines that work to kill cancer cells. The doctor may recommend chemotherapy if a patient is at risk of having the cancer spreading beyond the breast or if it already has spread. Chemotherapy is not used for cancers with a low risk of spreading to other parts of the body.

A patient may need chemotherapy if:

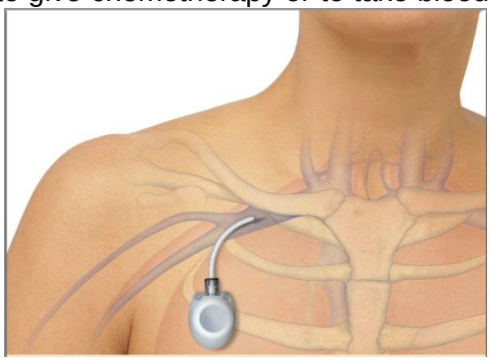
- The cancer was more than a centimetre in size
- There was cancer in the underarm lymph nodes.
- The cancer had the potential to grow quickly. This kind of cancer may be described on the pathology report by words like:

    - high grade
    - lymphatic invasion
    - vascular invasion
    - hormone-receptor-negative

- high growth rate
- HER2-positive

For men with hormone-receptor-positive cancer, hormonal therapy is usually the treatment of choice. If the cancer recurs or progresses on hormonal therapy, then chemotherapy may be added.

Chemotherapy may be given through a needle placed in the vein or by pills. The doctor may put in a 'port'. This is a plastic device that sits just under the upper chest or upper arm and empties into a blood vessel. A needle fits into the port to give chemotherapy or to take blood for tests.



[Picture Credit: Chemotherapy Port]

Chemotherapy may be given for a few days with a week or more off before the next dose. This cycle of treat-then-rest is repeated until the treatment course is finished. Depending on what medicines your doctor prescribes, the chemotherapy will usually be over in about 3-6 months.

Often two or more chemotherapy medications are used at the same time or one after the other. This will improve the chance of killing the different kinds of breast cancer cells that come from the same cancer. The medication combinations are known by the first letters in the medication names.

Here are a few of the most commonly used chemotherapy combinations:

- **AC±T:** Adriamycin (chemical name: doxorubicin) with Cytoxan (chemical name: cyclosphosphamide), with or without Taxol (chemical name: paclitaxel) or Taxotere (chemical name: docetaxel)
- **TAC:** involves the same medicines as above but in a different order
- **AT:** Adriamycin with Taxol or Taxotere
- **CMF:** Cytoxan, methotrexate, and fluorouracil (also called 5-FU or 5-fluorouracil)
- **CAF:** Cytoxan, Adriamycin, and fluorouracil
- **CEF:** Cytoxan, Ellence (chemical name: epirubicin), and fluorouracil
- **FAC or CAF:** fluorouracil, Adriamycin, and Cytoxan; these drugs are given in different orders

Other chemotherapy medicines that may be used alone or in combination include:

- **Xeloda** (chemical name: capecitabine): A pill taken to treat advanced (metastatic) breast cancer.
- **Gemzar** (chemical name: gemcitabine): Taken in combination with Taxol to treat advanced breast cancer.
- **Navelbine** (chemical name: vinorelbine): An intravenous (IV) chemotherapy that is used in patients with metastatic breast cancer. Navelbine is approved for second-line therapy — after an initial chemotherapy (first-line) regimen has been used and has stopped working.
- **Abraxane** (chemical name: albumin-bound or nab-paclitaxel): An injectable formulation of paclitaxel for treating metastatic breast cancer. Abraxane is approved as second-line therapy.

Targeted therapy - Medications that specifically target an abnormality within the cancer cells may be able to offer extra benefits and few side effects.

Herceptin (chemical name: trastuzumab) is the best known medicine of this type. Herceptin is an immune targeted therapy and works only against breast cancers that have extra HER2 genes and make too many HER2 protein receptors. These receptors work like parking spots on breast cancer cells. They receive signals telling the cells to grow and spread. Herceptin targets and blocks the parking places, so the signals to grow and spread cannot be delivered. Herceptin also hooks on to the cancer cells and 'marks' them. The immune system notices these marked cells and destroys them. Herceptin is very effective in people with HER2-positive breast cancer who have early- or late- (advanced) stage disease.

Herceptin has several potential side effects:

- It may cause flu-like symptoms (chills, fever, nausea, vomiting, headache, pain).
- It can sometimes cause heart damage. To minimise this risk, Herceptin is not given with other drugs that can also damage the heart. There is little risk to the heart when one takes Herceptin alone.

Avastin (chemical name: bevacizumab) is another targeted therapy. Avastin targets the new blood vessels that feed cancer cells. Avastin has been approved by the United States Food and Drug Administration (FDA) in combination with Taxol (chemical name: paclitaxel) to treat metastatic HER2-negative breast cancer in people who have not already received chemotherapy for metastatic breast cancer.

Avastin has a number of potentially serious side effects including high blood pressure, nose bleeds, and extra protein in the urine. Avastin also may increase the risk of stroke and heart problems. If one already has any of these conditions or are at high risk for them, talk to the treating doctor about this.

New targeted therapies are emerging on a regular basis.

Hormone therapy - Medicines that target hormone receptors in breast cancer cells are called hormonal therapies. This form of treatment can be very effective against hormone-receptor-positive breast cancer - having either oestrogen or progesterone receptors present in the cancer. Most breast cancers in men are hormone-receptor-positive.

The same kinds of hormonal therapies that work in women also work in men. The medicine with the longest track record is tamoxifen, which belongs to the selective oestrogen receptor modulator (SERM) group of medications. This medicine blocks the oestrogen receptor, keeping the hormone (oestrogen) from getting into the receptor and turning on cancer cell growth. Another form of hormonal therapy is the aromatase inhibitors. This category includes the medicines Arimidex (chemical name: anastrozole), Femara (chemical name: letrozole), and Aromasin (chemical name: exemestane).

Because breast cancer is so uncommon in men, there have been no clinical trials in men to figure out which medicine is best under each circumstance. The United States Food and Drug Administration (FDA) has not approved the medications discussed here for use in men, only for women. But these medicines can still be very effective in men dealing with hormone-receptor-positive disease. The extensive results of hormonal therapy in women can be applied to men dealing with the disease.

For men with early-stage, hormone-receptor-positive disease who are at significant risk of having the cancer come back (recur), hormonal therapies are usually prescribed for 5 years. The doctor might recommend tamoxifen or an aromatase inhibitor (Arimidex, Femara, or Aromasin). In light of the benefits women have had from extended hormonal therapy, men may also want to consider taking Femara for 5 years after 'graduating' from 5 years of tamoxifen.

Because there have been no men involved in the clinical trials for these medications, it is hard to know exactly what the potential side effects are. Some men have reported the following symptoms while taking hormonal therapies:

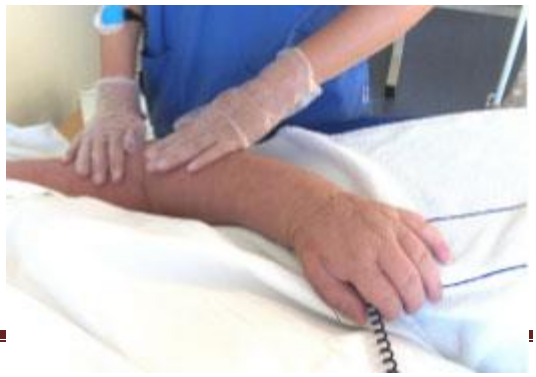
- loss of sexual desire
- trouble having an erection
- weight gain
- hot flashes
- mood swings

One major difference is that men with breast cancer respond much better to hormone therapy than women do. About 77% of male breast cancers have hormone receptors, meaning that hormone therapy can work in most men to treat the cancer.
(WebMD; Breastcancer.org).

Follow-up Care and Treatment for Breast Cancer in Men
After treatment for breast cancer ends, the patient should talk to his treating physician about developing a follow-up care plan. This plan may include regular physical examinations and/or medical tests to monitor recovery for the coming months and years. This could also include regular physical examinations to help keep track of the breast cancer treatment received and develop a survivorship care plan once treatment is completed. In some instances, patients may be seen at survivorship clinics that specialise in the post-treatment needs of people with cancer.

Breast cancer can come back in the breast or other areas of the body. The symptoms of a cancer recurrence include a new lump in the breast, under the arm, or along the chest wall; bone pain or fractures; headaches or seizures; chronic coughing or trouble breathing; extreme fatigue; and/or feeling ill. Talk with the doctor if any of these or other symptoms are experienced.

Picture Credit: Lymphoedema]



After surgery (mastectomy or lumpectomy) to treat breast cancer, the breast may be scarred and may have a different

shape or size than before surgery. If lymph nodes were removed as part of the surgery or affected during treatment, lymphoedema (swelling of the hand and/or arm) may occur, and this is a life-long risk for patients.

Some patients experience breathlessness, a dry cough, and/or chest pain two to three months after finishing radiation therapy because the treatment can cause swelling and fibrosis (hardening or thickening) of the lungs. These symptoms are usually temporary. Talk with a doctor if any new symptoms after radiation therapy occurs or if the side effects are not going away.

Patients who received trastuzumab or certain types of chemotherapy called anthracyclines may be at risk of heart problems. Talk with the doctor about the best ways to check for heart problems.

In addition, men recovering from breast cancer have other symptoms that may persist after treatment like cancer-related fatigue, a drop in cognitive function (sometimes called ATMP), and other late effects of cancer treatment.

Men recovering from breast cancer are encouraged to follow established guidelines for good health, such as maintaining a healthy weight, not smoking, eating a balanced diet, and having recommended cancer screening tests. Talk with a doctor to develop a plan that is best suits one's needs. Moderate physical activity can help rebuild strength and energy levels and may lower the risk of cancer recurrence. The doctor can help create a safe exercise plan based upon needs, physical abilities, and fitness level.
(Cancer.Net).

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.

Practically all breast cancer clinical trials (internationally) are open to men.

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 condition or situation. Readers of this document should seek appropriate medical advice prior to taking or refraining from taking any action resulting from the contents of this Fact Sheet. As far as permissible by South African law, the Cancer Association of South Africa (CASNA) accepts no responsibility or liability to any person (or his/her dependants/estate/heirs) as a result of using any information contained in this Fact Sheet.

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