Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet on Primary Peritoneal Cancer

Introduction

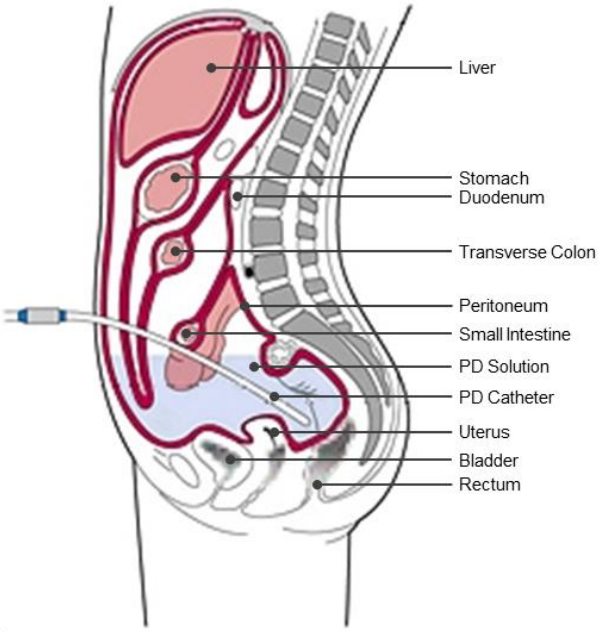
The peritoneum consists of the parietal peritoneum – a heterogeneous, serous, semi-permeable membrane that lines the abdominal wall – and the visceral peritoneum, which covers the abdominal organs (Figure 1). Its surface area is approximately 1-2 m^2.

In males, the peritoneum is a closed-sac system, whereas in females it is an open-sac system with the fallopian tubes and ovaries connecting to the peritoneal cavity.

[Picture Credit: Peritoneum]

The peritoneal cavity, located between the parietal and visceral peritoneum, contains approximately 100 mL of serous fluid and becomes the dialysate compartment during peritoneal dialysis (PD) from which exchange of solutes with the blood can occur.
(Advanced Renal Education Program).

Figure 1. Anatomy of the Peritoneum



Primary Peritoneal Cancer (PPC)

Primary peritoneal cancer (PPC) is a relatively rare cancer that develops most commonly in women. PPC is a close relative of epithelial ovarian cancer, which is the most common type of malignancy that affects the ovaries. The cause of primary peritoneal cancer is unknown.
It is important for women to know that it is possible to have primary peritoneal cancer even if their ovaries have been removed.

Primary peritoneal cancer (PPC) is a rare cancer of the peritoneum. It is very similar to the most common type of ovarian cancer called epithelial cancer. This is because the lining of the abdomen and the surface of the ovary come from the same tissue when humans develop from embryos in the womb. Doctors now think that most high grade serous cancers actually start in the far end of the fallopian tube rather than the surface of the ovary or peritoneum.

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PPC is a cancer that mainly affects women. There are no exact numbers of how many people get it. Research suggests that between 7 and 15 out of 100 women (7 to 15%) who have advanced ovarian cancer will actually have PPC. It is very rare in men. Most people are over the age of 60 when they are diagnosed.
(Cancer Research UK; Foundation for Women's Cancer).

Incidence of Primary Peritoneal Cancer (PPC) in South Africa
The South African National Cancer Registry (2013) does not provide any information regarding the incidence of Primary Peritoneal Cancer.

Link between Ovarian Cancer and Primary Peritoneal Cancer
Peritoneal cancer acts and looks like ovarian cancer. This is mainly because the surface of the ovaries is made of epithelial cells, as is the peritoneum. Therefore, peritoneal cancer and a type of ovarian cancer cause similar symptoms. Doctors also treat them in much the same way.

Despite its similarities with ovarian cancer, one can have peritoneal cancer even if one's ovaries have been removed. Peritoneal cancer can occur anywhere in the abdominal space. It affects the surface of organs contained inside the peritoneum.

The causes of peritoneal cancer are not known, however, there are different theories about how it begins. Some researchers believe it comes from ovarian tissue implants left in the abdomen during foetal development while others think the peritoneum undergoes changes that make it more like the ovaries.

Women at risk for ovarian cancer are also at increased risk for peritoneal cancer. This is even more likely if one has the BRCA1 and BRCA2 genetic mutations. Older age is another risk factor for peritoneal cancer.
(WebMD).

Signs and Symptoms of Primary Peritoneal Cancer (PPC)
Unfortunately, because of the vague nature of its symptoms, PPC is usually diagnosed in advanced stages of disease, when achieving a cure is difficult.

The symptoms of PPC are more commonly gastrointestinal rather than gynaecologic in nature, and include abdominal bloating, changes in bowel habits and an early feeling of fullness after eating.

When bloating is severe, nausea and vomiting may result. Occasionally, patients with PPC present with a blockage of the intestines related to tumour on or next to the bowels. Normal vaginal bleeding is infrequently seen in patients with PPC.
(Gynecologic Cancer Foundation).

Diagnosis of Primary Peritoneal Cancer (PPC)
In addition to asking about symptoms, your doctor will review your medical history and conduct a physical examination, which involves examining for abnormalities in these areas:

- Uterus
- Vagina
- Ovaries
- Fallopian tubes
- Stomach
- Bladder
- Colon and rectum

Tests include:
Ultrasound - high-frequency sound waves produce a picture called a sonogram

CA-125 blood test - this test measures levels of a chemical in the blood called CA-125. If levels are high, peritoneal or ovarian cancer may be present. But CA-125 can be high for other reasons. So, this test cannot confirm a diagnosis of these cancers

CT scan - a computer linked to an X-ray machine produces detailed pictures of the inside the body

Lower GI Series or Barium Enema - with this test, the patient first receives an enema containing a white, chalky solution called barium. This outlines the colon and rectum on an X-ray. It makes it possible to spot some tumours as well as other problems

Upper GI Series - with this test, barium is swallowed and the oesophagus, stomach, and duodenum (the first part of the small intestine) are outlined on an X-ray

Biopsy - a surgeon removes tissue by opening the abdomen during a laparotomy or by inserting tools through small holes in the abdomen (laparoscopy). A pathologist studies the tissue sample under a microscope to confirm a diagnosis of cancer

Paracentesis - in cases where surgery is not possible or ascites (presence of fluid in the peritoneal cavity) could be due to other causes, the doctor may instead remove fluid for examination under a microscope. This is called paracentesis

Ovarian and peritoneal cancers look the same under a microscope. So, the pattern and location of any tumours helps indicate which type of cancer is present.
(WebMD).

Staging of Primary Peritoneal Cancer (PPC)
Primary Peritoneal Cancer is closely related to epithelial ovarian cancer (most common type).It develops in cells from the peritoneum (abdominal lining) and looks the same under a microscope. It is similar in symptoms, spread and treatment.

Ovarian cancer is classified into the following categories (stages):

T-categories for ovarian cancer

Tx: No description of the tumour's extent is possible because of incomplete information

T1: The cancer is confined to the ovaries -- one or both

T1a: The cancer is only inside one ovary - it isn't on the outside of the ovary, it doesn't penetrate the tissue covering the ovary (called the capsule) and isn't in fluid taken from the pelvis

T1b: The cancer is inside both ovaries but doesn't penetrate to the outside and isn't in fluid taken from the pelvis (like T1a except the cancer is in both ovaries)

T1c: The cancer is in one or both ovaries and is either on the outside of an ovary, grown through the capsule of an ovary, or is in fluid taken from the pelvis

T2: The cancer is in one or both ovaries and is extending into pelvic tissues

T2a: The cancer has spread (metastasized) to the uterus and/or the fallopian tubes but isn't in fluid taken from the pelvis

T2b: The cancer has spread to pelvic tissues besides the uterus and fallopian tubes but it isn't in fluid taken from the pelvis

T2c: The cancer has spread to the uterus and/or fallopian tubes and/or other pelvic tissues (like T2a or T2b) and is also in fluid taken from the pelvis

T3: The cancer is in one or both ovaries and has spread to the abdominal lining outside the pelvis. This lining is called the *peritoneum*

T3a: The cancer metastases are so small that they cannot be seen except under a microscope

T3b: The cancer metastases can be seen but no tumour is bigger than 2 centimetres

T3c: The cancer metastases are larger than 2 centimetres)

T categories for fallopian tube cancer

Tx: No description of the tumour's extent is possible because of incomplete information

Tis: Cancer cells are only in the inner lining of the fallopian tube. They haven't grown into deeper layers. Also called carcinoma in situ

T1: The cancer is in the fallopian tube(s), but has not grown outside of them

T1a: The cancer is only inside one fallopian tube -- it has not grown through to the outside of the tube. It hasn't grown through the tissue covering the tumour (called the capsule) and isn't in fluid taken from the pelvis

T1b: The cancer is growing in both fallopian tubes -- it has not grown through to the outside of the tube. It hasn't grown through the tissue covering the tumour (called the capsule) and isn't in fluid taken from the pelvis (like T1a but with tumour in both tubes)

T1c: The tumour is in one or both fallopian tubes and has either grown through the outer wall of the tube or cancer cells are found in fluid taken from the pelvis

T2: The tumour has grown from one or both fallopian tubes into the pelvis

T2a: The cancer is growing into the uterus and/or the ovaries

T2b: The cancer is growing into other parts of the pelvis

T2c: The cancer has spread from the fallopian tubes into other parts of the pelvis and cancer cells are found in fluid taken from the pelvis (either from ascites or from washings obtained at surgery

T3: The tumour has spread outside the pelvis to the lining of the abdomen

T3a: The areas of cancer spread outside the pelvis can only be found when the area is biopsied and looked at under the microscope

T3b: The areas of spread can be seen with the naked eye, but are 2 cm or less in size (less than an inch)

T3c: The areas of spread are greater than 2 cm in size

N categories

N categories indicate whether or not the cancer has spread to regional (nearby) lymph nodes

Nx: No description of lymph node involvement is possible because of incomplete information

N0: No lymph node involvement

N1: Cancer cells are found in the lymph nodes close to tumour

M categories

M categories indicate whether or not the cancer has spread to distant organs, such as the liver, lungs, or non-regional lymph nodes

M0: No distant spread

M1: Cancer has spread to the inside of the liver, to the lungs, or other organs

Stage Grouping

Once a patient's T, N, and M categories have been determined, this information is combined in a process called stage grouping to determine the stage, expressed in Roman numerals from stage I (the least advanced stage) to stage IV (the most advanced stage). The following table illustrates how TNM categories are grouped together into stages. This stage grouping also applies to fallopian tube carcinoma.

Stage	T	N	M
I	T1	N0	M0
IA	T1a	N0	M0
IB	T1b	N0	M0
IC	T1c	N0	M0
II	T2	N0	M0
IIA	T2a	N0	M0
IIB	T2b	N0	M0
IIC	T2c	N0	M0
III	T3	N0	M0
IIIA	T3a	N0	M0
IIIB	T3b	N0	M0
IIIC	T3c	N0	M0
	Any T	N1	M0
IV	Any T	Any N	M1

(American Cancer Society; National Ovarian Cancer Coalition)

Treatment of Primary Peritoneal Cancer (PPC)
The treatment a patient may receive depends on a number of things including:

- The size of the cancer
- Where the cancer is in the abdomen
- The patient's general health

The treatment for PPC is the same as for advanced epithelial ovarian cancer. Because PPC is usually at an advanced stage when it is diagnosed it can be difficult to treat. The aim of treatment for advanced cancer is usually to shrink the cancer and control it for as long as possible.

The main treatments are:

Surgery - the aim of surgery is to remove as much of the cancer from the abdomen as possible before chemotherapy. This is called debulking surgery. Chemotherapy tends to work better when there are only small tumours inside the abdomen. The surgery usually includes removing your womb, ovaries, fallopian tubes, and the layer of fatty tissue called the omentum. The surgeon will also remove any other cancer that he/she can see at the time of surgery. This may include part of the bowel if the cancer has spread there.

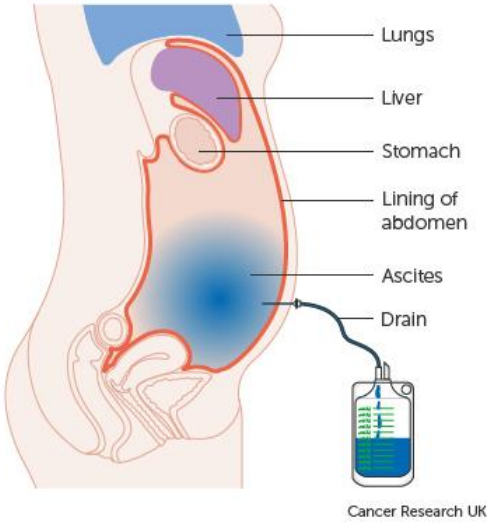
Chemotherapy - chemotherapy uses anti-cancer (cytotoxic) drugs to destroy cancer cells. These drugs work by disrupting the growth of cancer cells. The drugs circulate in the bloodstream around the body. One may have chemotherapy:

- Before surgery to reduce the size of the cancer
- After surgery when you have recovered
- On its own if you are unable to have surgery

The most common chemotherapy drugs used to treat PPC are a combination of carboplatin and paclitaxel (Taxol).

Radiotherapy - radiotherapy uses high energy waves to kill cancer cells. Radiotherapy is not often used for PPCs. But doctors may use it to shrink tumours and reduce symptoms.

Other treatments - if the patient is unable to have chemotherapy, he/she can still have treatment to control any symptoms, such as pain, weight loss, and fluid in the abdominal cavity. Fluid can build up between the two layers of the peritoneum. This fluid build-up is called ascites. It can be very uncomfortable and heavy. The doctor can drain the fluid off using a procedure called abdominal paracentesis or an ascitic tap. The diagram demonstrates this.
(Cancer Research UK).



Cancer Research UK

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.

<u>Use of Placebos</u>

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.

<u>Possible benefits of taking part in a clinical trial</u>

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).

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