Cancer Association of South Africa (CANSA)

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Fact Sheet on the Dangers of Alternative Cancer Treatment Utilising Vitamin B_{17}

Introduction

It is claimed that a chemical found in apricot kernels, Vitamin B_{17}, also known as 'Laetrile' and 'Amygdalin', all cyanide releasing substances, can cure cancer even though there is no evidence to support such claims.

Despite decades of research, dating back to the 1950s, there is no evidence that Laetrile or Amygdalin can treat tumours in animals or humans. Clinical trials in humans have failed to find any benefits. Proponents of Laetrile claim that cancer is caused by a vitamin deficit and that Laetrile, often referred to as Vitamin B_{17}, helps to fix that deficit. However, Laetrile is not a vitamin and it is not essential for good health. (iHeard.com).

Laetrile is a partly man made (synthetic) form of the natural substance Amygdalin. Amygdalin is a plant substance found naturally in raw nuts and the pips of many fruits, particularly apricot pips, or kernels. It is also present in plants such as lima beans, clover and sorghum.

Some people call Laetrile Vitamin B_{17}, although it is not a vitamin.

It also has the names:

- Mandelonitrile beta D gentiobioside
- Mandelonitrile beta glucuronide
- Laevorotatory
- Purasin
- Amygdalina
- Nitriloside

There is no scientific evidence to support claims that Laetrile or Amygdalin can treat cancer or any other illness. Despite this, it has been promoted as an alternative cancer treatment. Alternative treatment means that people use it instead of conventional cancer treatments such as cancer drugs or radiotherapy. The first use of Laetrile as a treatment for cancer was in Russia in 1845, and it was used in the USA from the 1920s.

In the 1970s, Laetrile was widely promoted as an anti-cancer agent either on its own or as part of a programme with a particular diet, high dose vitamin supplements, and pancreatic enzymes.

It is recommended that one should not replace conventional cancer treatment with any type of alternative cancer therapy, such as Laetrile. Laetrile can cause serious side effects in some people because of cyanide so it is not recommended that Laetrile be used alongside or instead of conventional cancer treatment.
(Cancer Research UK).

Other Sources of Cyanide
Cyanide is a rare, but potentially deadly poison. It works by making the body unable to use life-sustaining oxygen. Cyanide compounds that can be poisonous include hydrogen cyanide gas, and the crystalline solids, potassium cyanide and sodium cyanide.

Common sources of cyanide poisoning include:

- Smoke inhalation from fires
- Industries that use cyanide (photography, chemical research, synthetic plastics, metal processing, and electroplating)
- Plants (such as apricot pits and a type of potato called cassava)
- The cancer treatment laetrile, and
- Cigarette smoking.

(eMedicineHealth).

Uses of Cyanide
Cyanide is released from natural substances in some foods and in certain plants such as cassava, lima beans and almonds. Pits and seeds of common fruits, such as apricots, apples, and peaches, may have substantial amounts of chemicals which are metabolized to cyanide. The edible parts of these plants contain much lower amounts of these chemicals.

Cyanide is contained in cigarette smoke and the combustion products of synthetic materials such as plastics. Combustion products are substances given off when things burn.

In manufacturing, cyanide is used to make paper, textiles, and plastics. It is present in the chemicals used to develop photographs. Cyanide salts are used in metallurgy for electroplating, metal cleaning, and removing gold from its ore. Cyanide gas is used to exterminate pests and vermin in ships and buildings.

Hydrogen cyanide, under the name Zyklon B, was used as a genocidal agent by the Germans in World War II.

Reports have indicated that during the Iran-Iraq War in the 1980s, hydrogen cyanide gas may have been used along with other chemical agents against the inhabitants of the Kurdish city of Halabja in northern Iraq.
(Centers of Disease Control and Prevention).

Toxicity of Cyanide

Cyanide toxicity is generally considered to be a rare form of poisoning. However, cyanide exposure occurs relatively frequently in patients with smoke inhalation from residential or industrial fires. In addition, intensive treatment with sodium nitroprusside or long-term consumption of cyanide-containing foods is a possible source of cyanide poisoning. Historically, cyanide has been used as a chemical warfare agent, and it could potentially be an agent for a terrorist attack.

Depending on its form, cyanide may cause toxicity through inhalation, ingestion, dermal absorption, or parenteral administration. Clinical manifestations vary widely, depending on the dose and route of exposure, and may range from minor upper airway irritation to cardiovascular collapse and death within minutes. In severe cases, rapid, aggressive therapy consisting of supportive care and antidote administration can be lifesaving.
(Medscape).

Vitamin B_{17} and Cancer Treatment

Laetrile (also known as Vitamin B_{17}) is the name for a semi-synthetic compound which is chemically related to Amygdalin, a cyanogenic (cyanide producing) glycoside from the kernels of apricots and also from various other species of the genus *Prunus*. Laetrile and Amygdalin are promoted under various names for the treatment of cancer although there is no evidence for its efficacy. Due to possible cyanide poisoning, Laetrile and Amygdalin as well as so-called Vitamin B_{17} can be dangerous.

The term ‘Laetrile’ is used interchangeably with ‘Amygdalin’ to designate natural substances, derived primarily from apricots and other kernels that can release cyanide, which is lethal to living organisms.

The cyanogenic diglucoside, Amygdalin, has gained high popularity among cancer patients together with, or in place of, conventional therapy. Still, evidence based research on Amygdalin is sparse and its benefit controversial.

A retrospective analysis was conducted by Blaheta, *et al*., (2016) for Amygdalin relevant reports using the PubMed database with the main search term "Amygdalin" or "Laetrile", at times combined with "cancer", "patient", "cyanide" or "toxic". The researchers did not exclude any "unwanted" articles. Additionally, internet sources authorised by governmental or national institutions have also been included. The researchers concluded that no convincing evidence showing that Amygdalin induces rapid, distinct tumour regression in cancer patients, particularly in those with late-stage disease, is apparent. There was also no evidence that purified Amygdalin, administered in "therapeutic" dosage, causes toxicity. Multiple aspects of Amygdalin administration have not yet been adequately explored, making further investigation necessary to evaluate its actual therapeutic potential.

In the 1920s, Dr Ernst T Krebs (Senior) formulated a theory that Amygdalin could kill cancer cells. His theory was inconsistent with biochemical facts and has since been modified at least twice by his son, Ernst T Krebs (Junior). Extensive work has been done by cancer scientists to test the claims that Laetrile fights cancer. Many animal experiments in the 1970s showed a complete lack of tumour killing ability by Laetrile. Reviews of the medical records of patients whose cancers were claimed to be reduced or cured after Laetrile treatment found insufficient medical evidence to judge Laetrile's efficacy.

In a clinical trial among cancer patients reported in 1982, Laetrile neither caused shrinkage of tumours, nor increased survival time, neother alleviated cancer symptoms, nor enhanced well-being of any of the participants. Several reports, however, in the medical literature documented instances in which Laetrile caused serious, life-threatening toxicity when taken in large doses in the manner prescribed by Laetrile advocates.

A group of researchers found that various claims that Laetrile or Amygdalin has beneficial effects for cancer patients are not currently supported by sound clinical data. The researchers found that there is a considerable risk of serious adverse effects from cyanide poisoning after Laetrile or Amygdalin, especially after oral ingestion. The risk-benefit balance of Laetrile or Amygdalin as a treatment for cancer is, therefore, unambiguously negative. (Milazzo & Horneber, 2015; No Authors Listed, 1991).

Greenberg (1980) reviewed the evidence for the claims that Laetrile (Amygdalin) can prevent or control cancers. The beta-glucosidase content of cancer tissues is low compared to the tissues of normal liver and small intestine. Cancer tissues contain the enzyme *rhodanese* in amounts comparable to that of liver and kidney and hence, cannot be attacked selectively by cyanide release through beta-glucosidase action of Amygdalin. Amygdalin does not have the properties of a vitamin. Rats have been reared for several generations on diets devoid of cyanogenic glycosides, without developing neoplasms. Experiments with tumour-bearing rodents have demonstrated no curative properties by administration of the substance, Amygdalin.

Greenberg found that Amygdalin was not as non-toxic as claimed, particularly when ingested orally, and especially when taken with plant material high in beta-glucosidase. The claims for cure and control of cancers in humans were refuted. According to him, the writings of Laetrile proponents are also filled with erroneous and absurd statements.

In a study (Sauer, *et al*., 2015) found that the use of complementary and alternative medicine (CAM) is widespread in children with cancer and its use is poorly regulated. They describe a case of severe cyanide poisoning arising from CAM use. A severely agitated, encephalopathic, unresponsive 4-year-old boy (initial Glasgow Coma Scale of 3) with a history of metastatic ependymoma (a type of childhood brain cancer) was brought to the emergency department by ambulance services. Initial blood gas analysis demonstrated severe metabolic/lactic acidosis. On detailed questioning of the parents, the use of CAM including intravenous and oral "Vitamin B_{17}" (Amygdalin) and ingestion of apricot kernel was reported. After administering sodium thiosulfate, there was a rapid improvement in the child's medical condition with complete recovery without need for further intensive care treatment. His serum cyanide level was markedly elevated. Cyanide poisoning is known to cause severe encephalopathy in children receiving CAM treatment with substances containing cyanogenic glycosides.

In a research article by Kalyanaraman, *et al.,* (1983) there is a report of a 67-year-old woman with lymphoma who presented with a neuromyopathy following Laetrile (Amygdalin) treatment. She had significant elevation of blood and urinary thiocyanate and cyanide levels. Sural nerve biopsy specimen revealed a mixed pattern of demyelination (disintegration of the myelin sheath of nerve cells) and axonal degeneration. The latter being very prominent. Gastrocnemius muscle biopsy specimen showed a mixed pattern of denervation and myopathy with Type II atrophy upon histochemical examination.

Kalyanaraman and his fellow researchers concluded that cyanide toxicity, secondary to Laetrile therapy, and nutritional deficiency caused the neuromyopathy, as the changes in peripheral nerve observed in the 67-year old woman were similar to changes described in ataxic polyneuropathy occurring in Nigeria where it was attributed to high cyanide content in the diet and nutritional deficiency. The patient's clinical condition improved following discontinuation of Laetrile treatment. This supported the diagnosis that her condition was caused by Laetrile (Amygdalin).

In a clinical trial by Moertel, *et al*. (1982), one hundred and seventy-eight patients with cancer were treated with Amygdalin (Laetrile) plus a "metabolic therapy" programme consisting of diet, enzymes, and vitamins. The great majority of these patients were in good general condition before treatment. None was totally disabled or in pre-terminal condition. One third had not received any previous chemotherapy. The pharmaceutical preparations of Amygdalin, the dosage, and the schedule were representative of past and present Laetrile practice. No substantive benefit was observed among the patients in terms of cure, improvement or stabilisation of cancer, improvement of symptoms related to cancer, nor extension of life span.

The hazards of Amygdalin therapy were evidenced in several of the patients through symptoms of cyanide toxicity or by blood cyanide levels approaching lethal range. The researchers concluded that Amygdalin (Laetrile) was a toxic drug that was not effective as a treatment for cancer.

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).

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