

The Biomarkers Consortium
Advancing Medical Science

FACT SHEET

Disease Burden and Potential of Biomarkers

Cancer

Disease Basics: Cancer occurs when cells continue to grow and divide and do not die when they should. Cancer cells can damage or destroy nearby tissues and can metastasize (spread) to distant parts of the body through the bloodstream or lymphatic system. Cancer can cause a variety of symptoms. Cancer can be treated with surgery, radiation therapy, chemotherapy, hormones, and/or biological therapy.

Incidence: About 1.4 million new cases of cancer were diagnosed in the United States in 2005, and more than 550,000 people died of the disease. Cancer is the second leading cause of death in this country. About 64 percent of all people diagnosed with cancer will be alive five years after diagnosis.

Potential for biomarkers: Cancer is the result of changes in the genes that control normal cell growth and death. These changes may be inherited, or may result from environmental or lifestyle factors. The genetic changes can also be used as biomarkers for diagnosis and to guide treatment decisions. Improvements in cancer detection, diagnosis, and treatment have increased the survival rate for many types of cancer. Increasingly, new approaches to cancer involve biomarkers. For example, biomarkers can be used to determine which patients will respond best to which treatments or will suffer serious side effects.

Depressive Disorder

Disease Basics: Major depression is manifested as a combination of symptoms that interfere with the ability to work, study, sleep, eat, and enjoy once pleasurable activities. Such a disabling episode of depression may occur only once but more commonly occurs several times in a lifetime. Depressive illnesses often interfere with normal functioning and cause pain and suffering not only to those who have a disorder, but also to those who care about them. Serious depression can destroy family life as well as the life of the ill person, but much of this suffering is unnecessary.

Most people with a depressive illness do not seek treatment, although the great majority even those whose depression is extremely severe, can be helped. Thanks to years of fruitful research, there are now medications that ease the pain of depression. In some families, major depression seems to occur generation after generation. However, it can also occur in people who have no family history of depression. Whether inherited or not, major depressive disorder is often associated with changes in brain structures or brain function. In recent years, researchers have shown that physical changes in the body can be accompanied by mental changes as well. Medical illnesses such as stroke, a heart attack, cancer, Parkinson's disease, and hormonal disorders can cause depressive illness, making the sick person apathetic and unwilling to care for

his or her physical needs, thus prolonging the recovery period. A serious loss, difficult relationship, financial problem, or any stressful (unwelcome or even desired) change in life patterns can trigger a depressive episode. Very often, a combination of genetic, psychological, and environmental factors is involved in the onset of a depressive disorder. Later episodes of illness typically are precipitated by only mild stresses, or none at all.

Incidence: Depressive disorders represent the largest single source of disability for Americans between ages 15 and 44 (WHO, 2002). In any given 1-year period, 9.5 percent of the population, or about 20.9 million American adults, suffer from a depressive illness. A recent Institute of Medicine report (2003) cites a 4 percent suicide rate for depression, a major source of the 30,000 suicides each year in the U.S. (compared to 18,000 homicides). Moreover, depression increased the rate of cardiovascular death, the morbidity from diabetes, and the prevalence of osteoporosis.

Potential for biomarkers: Currently, treatment of depression is trial and error, with 12 weeks needed to identify non-response to a given drug. Genomic biomarkers as predictors of response should allow clinicians to tailor treatments to each individual's likelihood of response or vulnerability to side-effects, saving patients much pain and suffering.

Diabetes and Pre-Diabetes

Disease Basics: Type 1 diabetes, formerly called juvenile diabetes or insulin-dependent diabetes, is usually first diagnosed in children, teenagers, or young adults. In this form of diabetes, the beta cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them. Type 2 diabetes, formerly called adult-onset or noninsulin-dependent diabetes, is the most common form of diabetes. People can develop type 2 diabetes at any age, even during childhood. This form of diabetes usually begins with insulin resistance, a condition in which fat, muscle, and liver cells do not use insulin properly. At first, the pancreas keeps up with the added demand by producing more insulin. In time, however, it loses the ability to secrete enough insulin in response to meals.

Being overweight and inactive increases the chances of developing type 2 diabetes. Gestational Diabetes can develop in women late in pregnancy. Although this form of diabetes usually goes away after the baby is born, a woman who has had gestational diabetes is more likely to develop type 2 diabetes later in life. Gestational diabetes is caused by the hormones of pregnancy or a shortage of insulin. Pre-diabetes is the state where an individual's blood glucose is higher than normal but lower than the diabetes range. It puts one at risk for getting type 2 diabetes and heart disease and can be treated if detected.

Incidence: About 7 percent of the US population and more than 20 percent of people 20 years or older have diabetes and one third of these are undiagnosed (CDC 2005 diabetes fact sheet). More than 40 million people in the United States, ages 40 to 74, have pre-diabetes and almost all are undiagnosed (American Diabetes Association). The latest estimate by the WHO shows that in 2000 worldwide there were 177 million diabetics, and this number will increase to at least 300 million by 2025. Much of this increase will occur in developing countries.

Potential for biomarkers: Early diagnosis is crucial for reducing the overall burden of type 2 diabetes. A more simplified and less burdensome approach to the diagnosis of diabetes and pre-diabetes than currently available would facilitate increased recognition and improved care of these conditions.