The Value of Investment in Health Care

Better Care, Better Lives

Executive Summary

Over the past few decades, significant advances in the U.S. health care system have helped people live longer and better lives. In fact, both mortality and disability rates have fallen consistently since the 1970s. This period has also seen substantial increases in health spending. All too often, health care discussions seem to center on the substantial increase in per person spending on health care during this period (Figure 1), rather than the benefits of improved health care that the spending brought.

Executive Summ

A focus on costs merely as a problem overlooks the value that patients and society in general derive from improved health. While costs are undoubtedly an important part of the health care debate, they should be considered in the context of the benefits achieved.

The Value of Investment in Health Care attempts to spur such a discussion by focusing on overall improvements in health as well as taking a specific look at four conditions (heart attack, type 2 diabetes, stroke, and breast cancer) that are among the most common causes of death and disability (Figure 2). The study suggests that the value of improved health in the U.S. population over the past 20 years significantly outweighs the additional health care expenditures that accompanied the improvements. In this report, we seek to answer a basic question that frequently goes unaddressed in the current debate: Is our increased health care spending worth it? The findings of this study show that the answer clearly is "Yes."

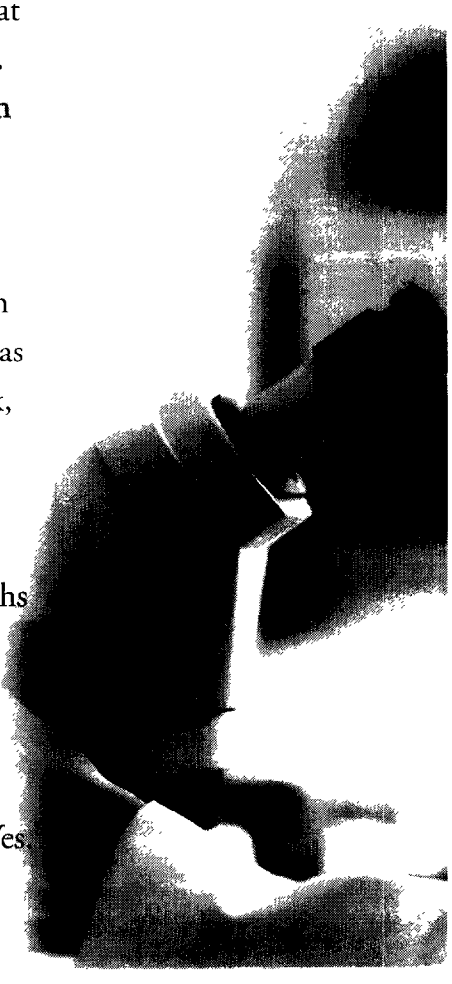

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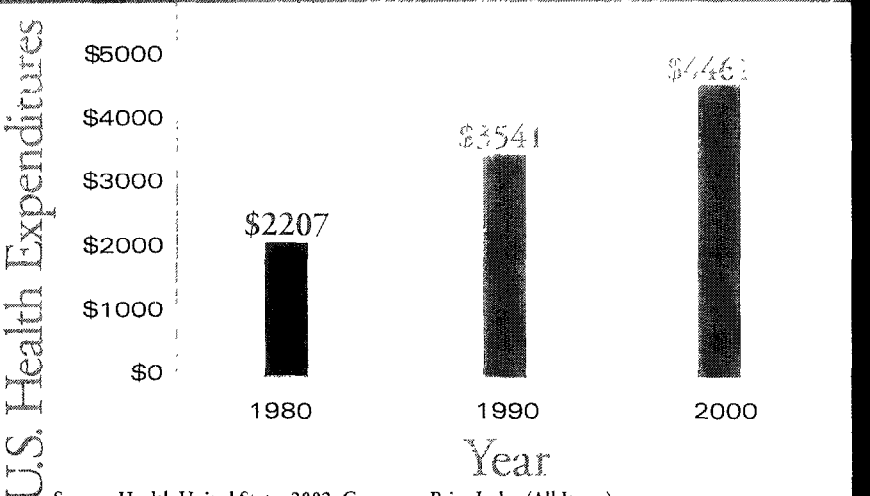
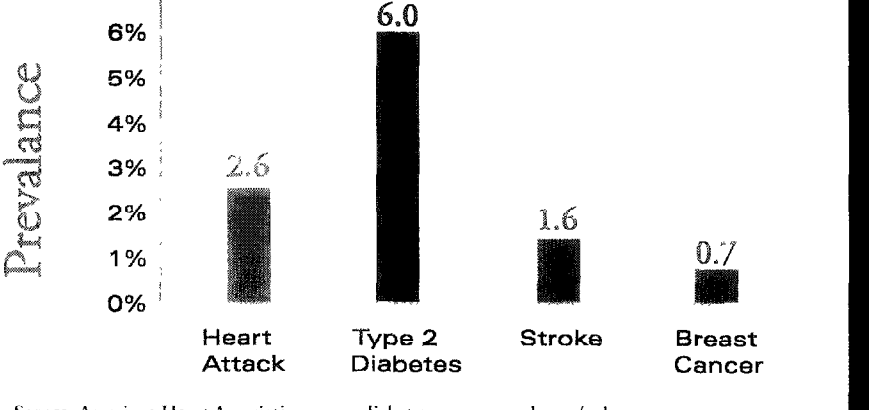
Figure 1 U.S. Health Care Expenditures per Person (2000 U.S. $)



Source: Health United States 2002; Consumer Price Index (All Items)

Figure 2 Percent (%) of U.S. Population in 2003 Affected by Conditions Studied



Source: American Heart Association; www.diabetes.org; www.cdc.gov/nchs

Summary of Findings

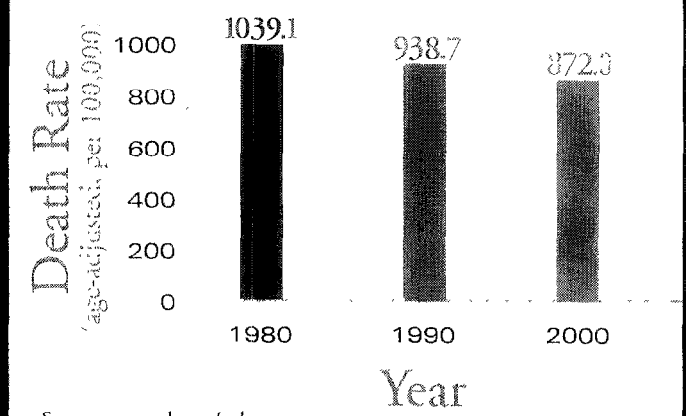
Overall Health

Our analysis suggests that, in the past 20 years, each additional dollar spent on health care services has produced health gains valued at $2.40 to $3.00.

Annual age-adjusted per person health care costs between 1980 and 2000 increased by $2,254 (102%), but this was accompanied by significant health gains, including:

- Annual death rates declined from 1,039.1 to 872 per 100,000 persons (16%), as shown in Figure 3.
- Life expectancy from birth increased by 3.2 years (4%), as shown in Figure 4.
- Disability rates for people over 65 years declined from 26.2 to 19.7 per 100 persons (25%), as shown in Figure 5.
- Number of days in the hospital, a measure of population health, fell from 129.7 to 56.6 per 100 persons (56%).
- Death rates in three of the diseases discussed in this report have fallen in the past 20 years. Death rates for type 2 diabetes have risen throughout the 1990s, coupled with an increase in the incidence of obesity.

Figure 3 Decline in Death Rates, 1980-2000

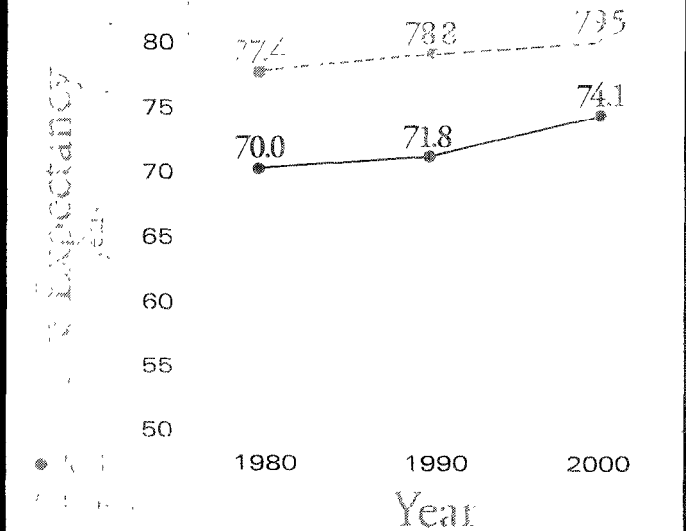


Source: www.cdc.gov/nchs

Simply put, without the above improvements in health and the associated investment, the U.S. would have spent $634 billion less on health care in 2000, but we would have experienced:

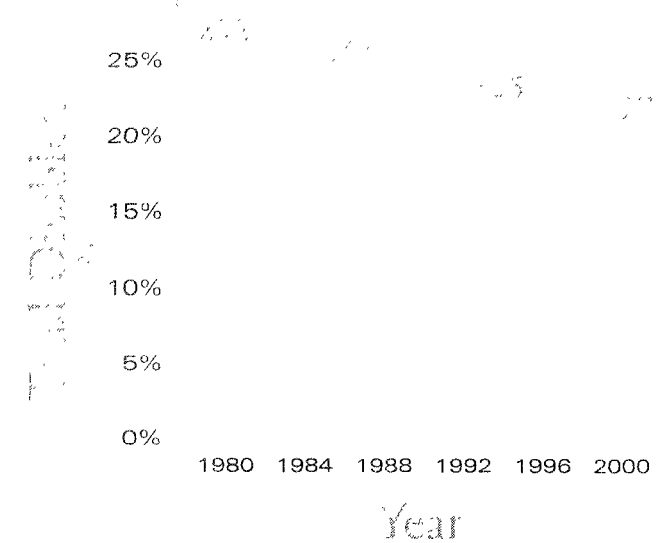
- 470,000 more deaths,
- 2.3 million more people with disabilities, and
- 206 million more days spent in the hospital.

Figure 4 Increase in Life Expectancy from Birth, 1980-2000

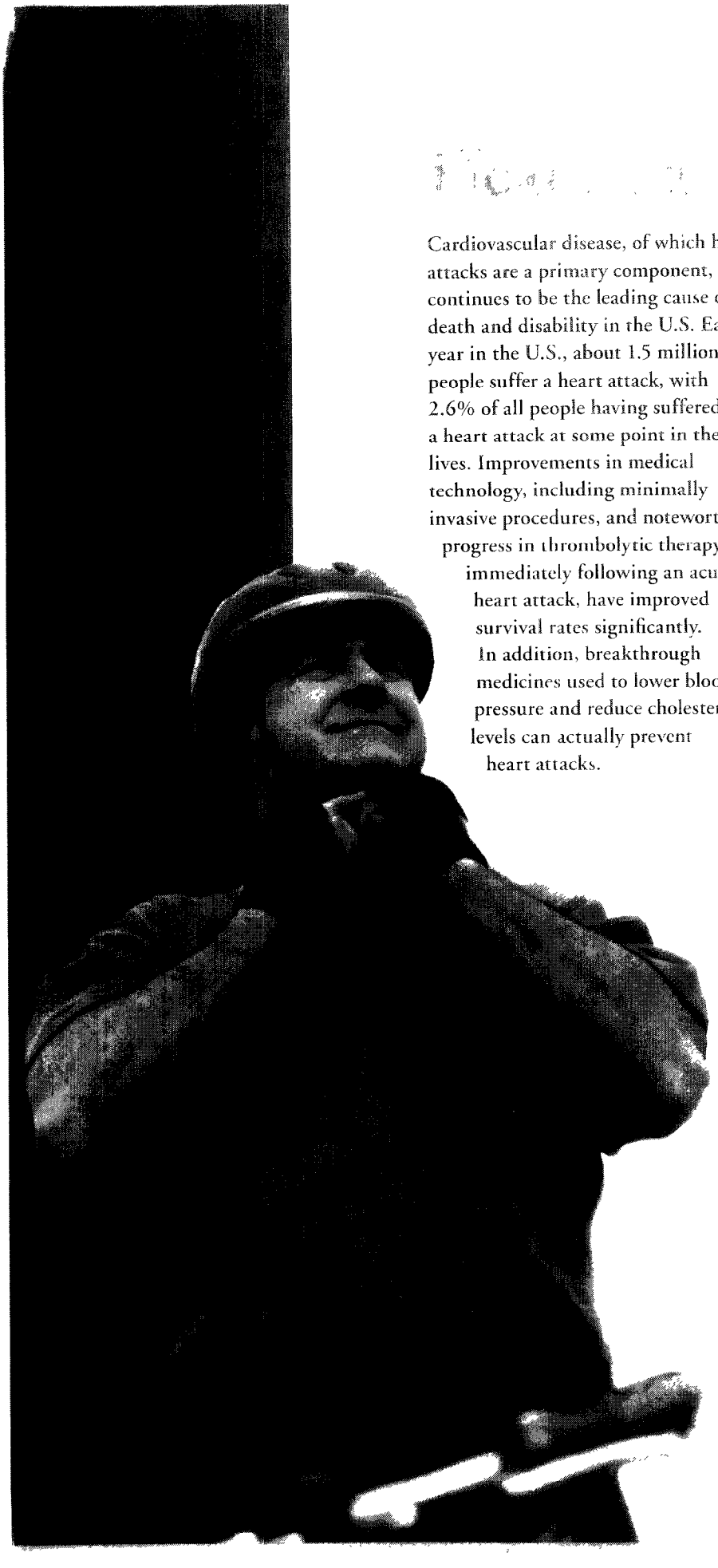


Source: Health United States, 2002

Figure 5 Decline in Disability Rates for People Aged Over 65 Years, 1982-2000



Source: Manton et al. 2001



Heart Attack

Cardiovascular disease, of which heart attacks are a primary component, continues to be the leading cause of death and disability in the U.S. Each year in the U.S., about 1.5 million people suffer a heart attack, with 2.6% of all people having suffered a heart attack at some point in their lives. Improvements in medical technology, including minimally invasive procedures, and noteworthy progress in thrombolytic therapy immediately following an acute heart attack, have improved survival rates significantly. In addition, breakthrough medicines used to lower blood pressure and reduce cholesterol levels can actually prevent heart attacks.

Based on a study of claims data for Medicare patients who suffered a heart attack, *every additional dollar spent on the overall treatment of heart attack has produced health gains valued at $1.10.*

Evidence of the value of health gains associated with specific investments in the management of heart attack includes

- Every additional dollar spent on statin therapy in heart attack survivors (vs. survivors treated with usual care) has produced health gains valued as high as $9.44.
- Every additional dollar spent on the routine use of beta-blockers (vs under-use) in patients suffering acute heart attacks has produced health gains valued as high as $38.44.

Some of the key innovations in the treatment of heart attacks include:

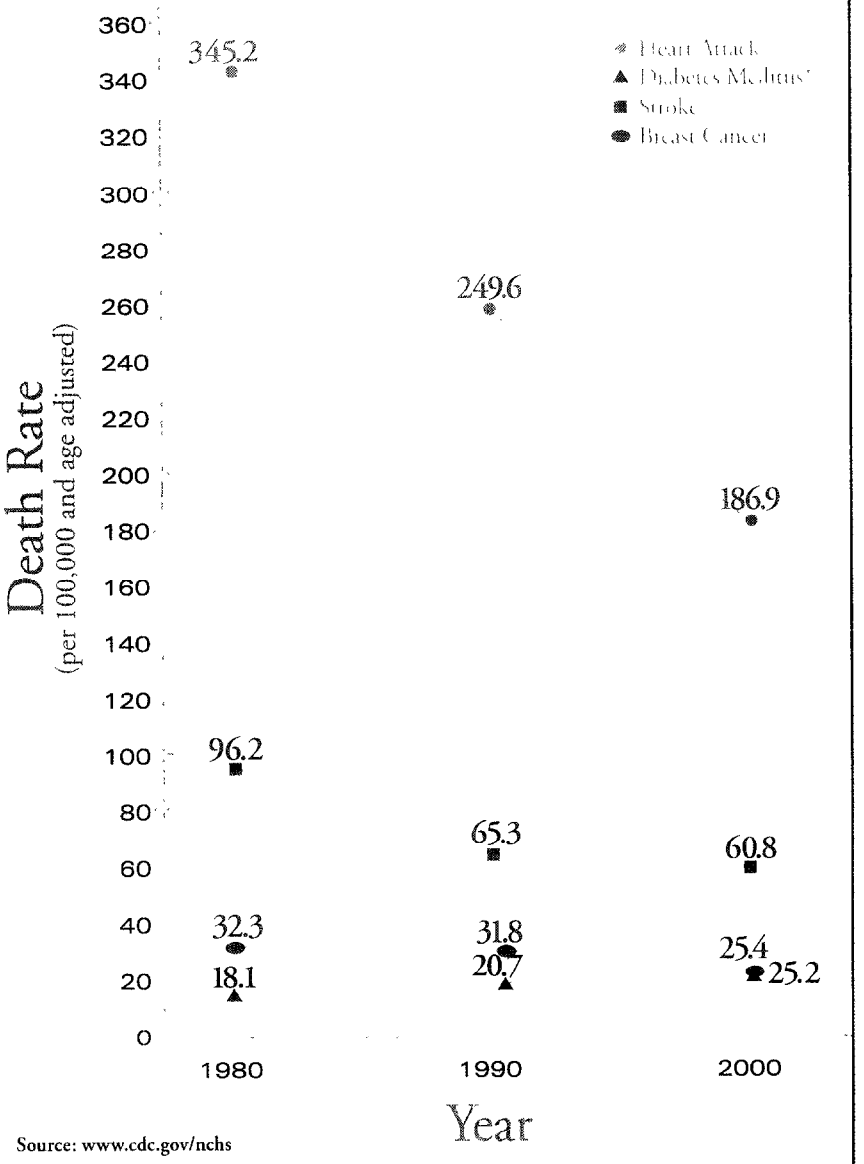
- Therapy for patients with heart attacks has improved dramatically with the introduction of newer, safer "clot-busting" agents.
- Diagnostic imaging technologies and procedures (e.g., ultrasound and cardiac catheterization) provide critical information on heart functioning and performance, which aids in treatment
- Percutaneous coronary interventions (PCIs), such as primary and conventional angioplasty with and without stents, improve survival in heart attack patients and provide an alternative to open-heart procedures (e.g., coronary artery bypass graft)

- Intravenous glycoprotein inhibitors are used during PCIs as prevention against clotting of blood.
- Several different therapies are routinely used as maintenance therapy to prevent recurrent heart attacks:
  - Short-term therapy with antiplatelets to prevent blood clots;
  - Antihypertensive agents (e.g., ACE inhibitors, angiotensin receptor blockers, beta-blockers) to control blood pressure; and
  - Statin therapy to lower lipid levels.

Advances in treatment have improved health outcomes for heart attack patients.

- Mortality due to heart attacks has been cut by more than half over the past 20 years, with rates falling from 345.2 to 186.9 per 100,000 persons (Figure 6).
- Early initiation of treatment with statins following an acute heart attack reduces the risk of fatal heart disease or a recurrent heart attack by 24%.
- Implantable cardiac defibrillators, which now can be implanted without open heart surgery, treat life-threatening irregular heart rhythms and reduce the risk of sudden cardiac death.
- Maintenance therapy with beta-blockers in patients who have suffered a heart attack leads to a reduction of 22% in one-year mortality rates.

Figure 6 Death Rates for Conditions Studied, 1980-2000



Source: www.cdc.gov/nchs

*** Mortality statistics from the CDC do not distinguish between type 1 and type 2 diabetes. However, 90% of all diabetes diagnoses are for type 2 diabetes, suggesting most of the diabetes-related deaths are most likely due to type 2.**

- The use of glycoprotein inhibitors has been shown to reduce the risk of death, a second heart attack, or need for revascularization by 48% in patients who have suffered a first heart attack.

Type 2 Diabetes

Type 2 diabetes (also known as non-insulin-dependent diabetes mellitus), is the most common form of diabetes, affecting 17 million people in the U.S., or roughly 6% of the population. Unfortunately, poorly managed diabetes can result in long-term complications such as diseases of the eye, kidney, and nervous system, as well as cardiovascular disease. These complications can lead to blindness, nerve damage, kidney failure, heart attack, stroke, and death. In the past few years, substantial progress has been made in understanding the risk factors for diabetes.

Based on a study of claims data for Medicare patients with type 2 diabetes, *every additional dollar spent on the overall treatment of type 2 diabetes has produced health gains valued at $1.49.*

Evidence of the value of health gains associated with specific investments in management of type 2 diabetes includes:

- Every additional dollar spent on intensive blood glucose control in newly diagnosed type 2 diabetic patients has produced health gains valued at $3.77.
- Every additional dollar spent on statin therapy in type 2 diabetics who also suffer from high cholesterol has produced health gains valued at $3.00.
- Every additional dollar spent on the screening and treatment of diabetic eye disease in type 2 diabetes patients on insulin has produced health gains valued at $36.00.

The management of type 2 diabetes has evolved significantly over the past few decades, due most recently to an increased understanding of risk factors:

- Advances in self-monitoring blood glucose kits, more accurate hemoglobin A1c tests, and more effective insulin and oral drug therapies have made tight blood glucose control possible.
- Tight control of blood pressure has been identified as an integral part of type 2 diabetes management.
- Statin therapy is routinely used in patients with type 2 diabetes to reduce elevated cholesterol levels

Overall mortality rates for diabetes mellitus have steadily increased over the past 20 years from 18.1 to 25.2 per 100,000 persons, given the increase in the incidence of type 2 diabetes.* However, interventions in type 2 diabetes are expected to improve outcomes by diminishing the risks and occurrence of long-term complications, as shown in several recent studies:

- Stringent control of blood glucose levels leads to reductions in risks for any diabetes-related complication (12%), any diabetes-related death (10%), death due to any reason (6%), and all microvascular complications, including eye, nerve, and kidney disease (25%).
- Tight blood pressure control in type 2 diabetes patients with high blood pressure leads to reductions in all diabetes complications (24%), deaths due to diabetes (32%), strokes (44%), heart failure (56%), and all microvascular complications, including eye, nerve and kidney disease (37%).
- When cholesterol is lowered with statin therapy, the risk of coronary events is reduced by 25% in type 2 diabetes patients.

* Mortality statistics from the CDC do not distinguish between type 1 and type 2 diabetes However, 90% of all diabetes diagnoses are for type 2 diabetes, suggesting most of the diabetes-related deaths are most likely due to type 2.

Stroke

Stroke is the third leading cause of death in the U.S. and the leading cause of adult disability; roughly 1.6% of the U.S. population have suffered a stroke. Two-thirds of stroke survivors suffer from significant long-term physical and emotional disabilities. Given the impact of stroke on victims and their families, progress in prevention, diagnosis, and treatment is critical. To this end, significant advances in diagnosis and therapy have improved patient care and reduced the mortality rate from stroke.

Based on a study of claims data for Medicare patients who suffered from stroke, *every additional dollar spent on the overall treatment of stroke has produced health gains valued at $1.55.*

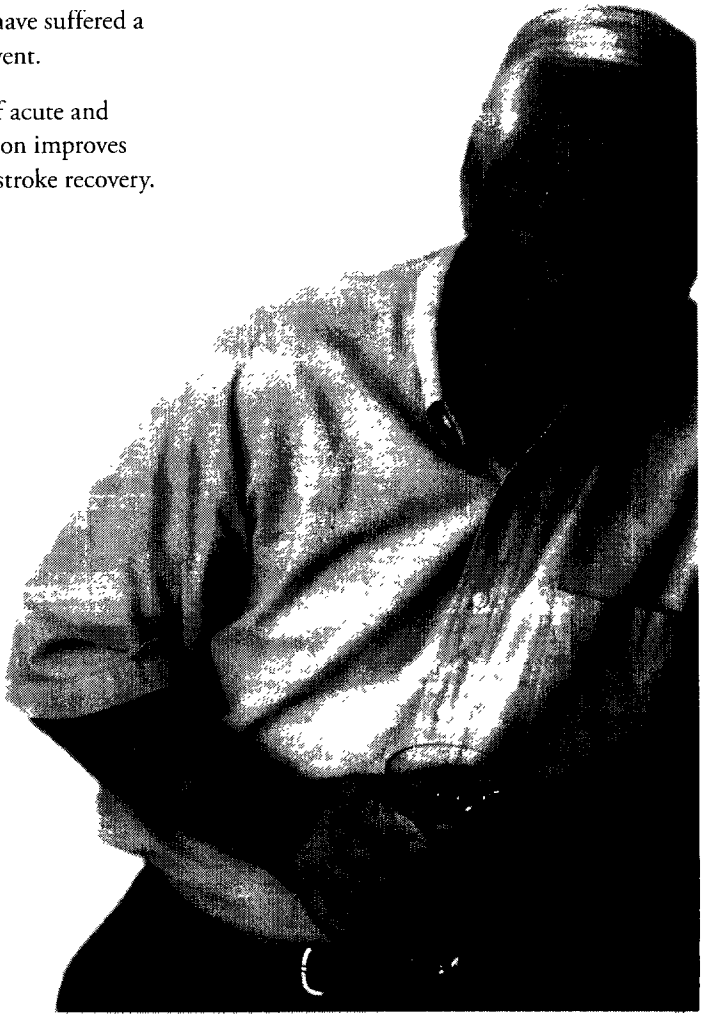
Evidence of the value of health gains associated with specific investments in management of stroke suggests that every additional dollar spent on antiplatelet therapy vs. aspirin for the prevention of stroke in high-risk patients has produced health gains valued at $2.00 to $6.00.

Some of the noteworthy progress in the management of stroke includes:

- Advances in surgical techniques (e.g., carotid endarterectomy, early aneurysm surgery, minimally invasive microcoil devices used to treat brain aneurysms) and better drug therapy (e.g., combination therapy with dipyridamole and aspirin, anticoagulants, and antithrombolytics) are expected to reduce the incidence of stroke, both primary stroke in high-risk patients and recurrent stroke in patients previously suffering a stroke.
- "Clot-busting" therapy is routinely used immediately following acute stroke.
- Advances in brain and vascular imaging—such as computed tomography (CT) and magnetic resonance imaging (MRI) scans of the brain and ultrasound images of the vessels—enable more rapid diagnosis and treatment of stroke.
- Glycoprotein inhibitors are often used to reduce the risk of recurrent coronary events (such as stroke) in individuals who have suffered a primary coronary event.
- The increased use of acute and subacute rehabilitation improves and speeds up post-stroke recovery.

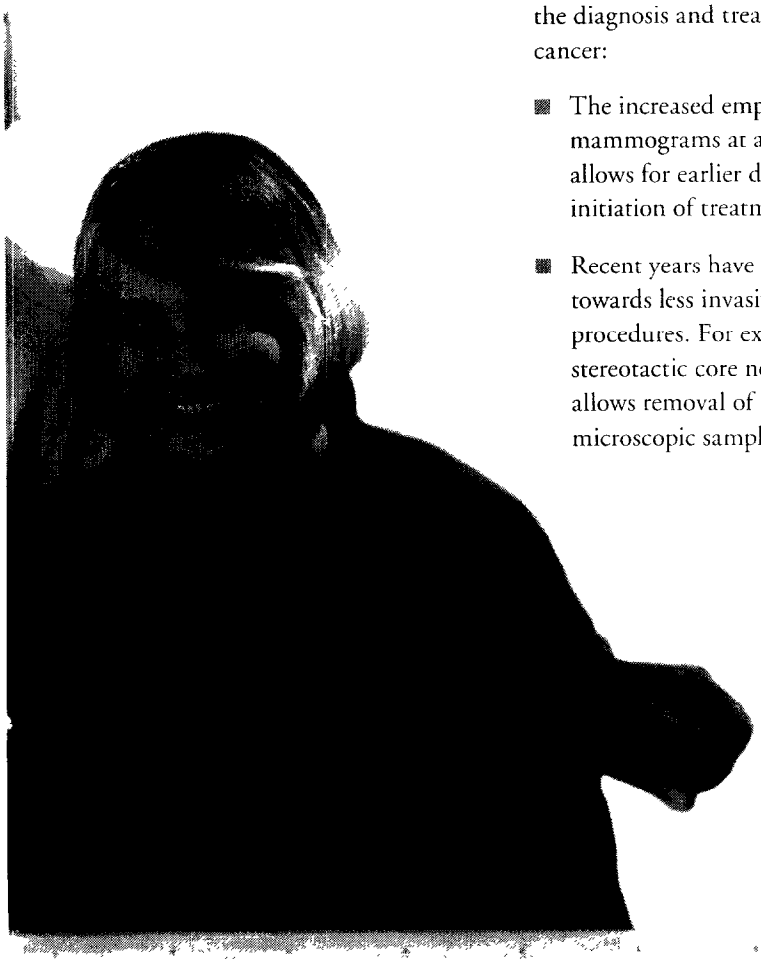
This progress has led to improved outcomes for stroke survivors.

- Stroke mortality rates have significantly declined in the past 20 years, falling from 96.2 to 60.8 per 100,000 persons, as shown in Figure 6.
- Due to the reduced mortality rates, the estimated number of non-institutionalized stroke survivors increased by 400,000 (from 2.0 to 2.4 million) between 1980 and 1991.



Breast Cancer

Breast cancer is one of the most commonly diagnosed cancers among women in the U.S., affecting 2.2 million women out of a total of 143.4 million women (1.5% among all women in the U.S.; 0.7% of the entire U.S. population) in 2000. About 40% of these women lived with breast cancer for 10 or more years. In 2001 alone, an estimated 192,000 new cases of invasive breast cancer were diagnosed. While substantial progress has been made in diagnosing and treating breast cancer, researchers continue their efforts to improve the outcomes for women affected by this disease.



Based on a study of claims data for Medicare patients with breast cancer, *every additional dollar spent on overall breast cancer treatment has produced health gains valued at $4.80.*

Evidence of the value of health gains associated with specific investments in breast cancer management includes:

- Every additional dollar spent on stereotactic core needle biopsy (vs. surgical biopsy) has produced health gains valued at $3.70 to $4.83.
- Every additional dollar spent on newer, less toxic hormonal therapy has produced health gains valued at $27.03 to $36.81.

The period since the 1970s has seen the following noteworthy advances in the diagnosis and treatment of breast cancer:

- The increased emphasis on mammograms at an earlier age allows for earlier diagnosis and initiation of treatment.
- Recent years have seen a shift towards less invasive diagnostic procedures. For example, stereotactic core needle biopsy allows removal of only a microscopic sample.
- Breast-conserving surgery offers a greatly improved cosmetic and psychological outcome over the traditional, more invasive mastectomy.
- New and better-tolerated hormonal treatments (used to block the effects of estrogen on the growth of cancer cells) improve rates of cancer-free survival without major side effects.

As the health interventions for breast cancer have advanced, health outcomes have improved.

- Overall mortality from breast cancer has declined from 32.3 in 1980 to 25.4 deaths in 2000 per 100,000 persons, as shown in Figure 6.
- Five-year survival rates have increased from 76.9% in 1980 to 86.6% in 1995.
- For a 54-year-old woman diagnosed with lymph node-positive breast cancer, the risk of developing metastatic disease has declined from 40% to 15%.

Conclusion

Expressed in dollar terms, the value of improved health in the U.S. population over the past 20 years significantly outweighs the additional health care expenditures during this period. *The Value of Investment in Health Care* adds further significant evidence showing that our increased spending on health care is well worth the cost. This evidence is consistent with economic theory: continued investment in health care reveals society's preference and implicit belief that the expected benefits are worth the costs. Over the past 20 years, patients have benefited from longer, better lives, as well as reduced disability and less hospitalization. The value of these improvements alone, which do not capture all the patient and societal benefits provided through health care, far outweigh increases in health care spending.

This report underscores a critical fact that must be part of every health policy discussion: health benefits have ***clear, quantifiable, economic*** value. Such policy discussions should encompass elements of not only costs of health care, but also the added benefits. Policymakers in the U.S. are increasingly interested in whether, and the degree to which, investments in health care are worth the costs. This report provides important new findings that quantify improvements in health resulting from these investments. These improvements and this report represent an essential element of the debate over health care costs, building upon a growing body of evidence that suggest these benefits are, indeed, worth the costs.

Glossary

ACE Inhibitor (ACEI) – Class of drugs used to lower blood pressure by inhibiting angiotensin-converting enzymes (ACEs), which help the conversion of angiotensin to angiotensin II.

Aneurysm – Localized widening/ballooning-out of a vessel, resulting in a "bulge" that can weaken the vessel's wall and cause a rupture; may occur in the brain, increasing blood pressure and resulting in a stroke.

Angiotensin II Receptor Blocker (ARB) – Class of drugs used to lower blood pressure by blocking angiotensin (eventually converted to angiotensin II), which causes blood vessels to constrict, raising heart rate and blood pressure.

Angioplasty – Procedure that re-opens blocked/narrowed arteries to the heart by using a catheter to insert a balloon in the blocked/narrowed portion of the artery; the balloon is then inflated to widen the artery. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Antiplatelet – Class of drugs that inhibit blood clot formation by keeping platelets (the body's natural blood-clotters) from binding together; also known as "clot-busting" drugs.

Beta-blocker – Class of drugs used to lower blood pressure by blocking beta receptors on the surface of heart cells.

Cardiac catheterization – Process to examine the heart by inserting a thin tube/hollow needle (catheter) into a vein or artery and passing it into the heart, often to open blockages.

Carotid endarterectomy – Surgery to remove plaque build up in the carotid arteries.

Computed Tomography (CT) – Method of examining body organs by scanning them with X-rays and then using a computer to construct an image based on the X-rays.

Coronary Artery Bypass Graft (CABG) – Procedure used to re-route blood supply around a blocked section of a coronary artery by removing healthy blood vessels from another part of the body (e.g., leg or chest wall) and surgically attaching these vessels to the diseased artery in such a way that blood flows around the blocked section.

Glucose – Sugar.

Glycoprotein inhibitor – Class of drugs that inhibit proteins that cause clot formation; often used in the management of cardiovascular patients.

Hemoglobin A1c – Measure of blood glucose levels captured in a lab evaluation that provides an average of blood glucose levels over 2-3 months.

Implantable Cardiac Defibrillator (ICD) – Device that delivers pacing or electric countershock to the heart when an abnormal rhythm is detected.

Magnetic Resonance Imaging (MRI) – Method of gathering images of body organs by using nuclear magnetic resonance of protons to produce proton density images.

Mastectomy – Complete removal of the breast.

Microcoil surgery – Minimally invasive surgical procedure used to treat aneurysms, which can often lead to stroke if left untreated.

Microvascular complications – Collective term that refers to diabetic retinopathy, neuropathy, and nephropathy.

Percutaneous Coronary Intervention (PCI) – Collective term used to describe minimally invasive cardiovascular procedures, such as angioplasty and stenting.

Percutaneous Transluminal Coronary Angioplasty (PTCA) – See angioplasty.

Revascularization – Process to restore blood flow to a body part through angioplasty, stents, coronary artery bypass graft or by dissolving blood clots with drug therapy.

Statin – Class of drugs that lower cholesterol levels by blocking enzymes essential to cholesterol production.

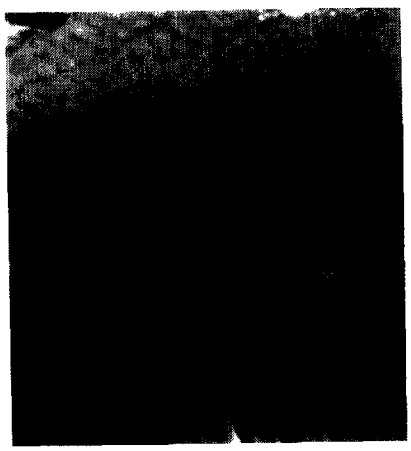
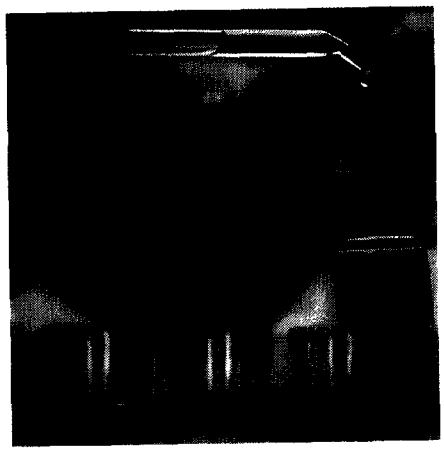
Stent – Tiny wire mesh device used to keep blood vessels open; classified as either bare-metal or drug-eluting.

Stereotactic core needle biopsy – Procedure to obtain tissue sample by taking two separate X-rays of the breast to locate the lump, and then, with only local anesthetic, using a needle to obtain a tissue sample.

Thrombolysis – Process of dissolving blood clots through drug therapy.

Thrombolytic – Drug used to dissolve or break up clots that block blood flow; also known as "clot-busting" drug.

Ultrasound – High-frequency sound vibration that can be translated into an image and is often used to make medical diagnoses.


The Value of Investment in Health Care

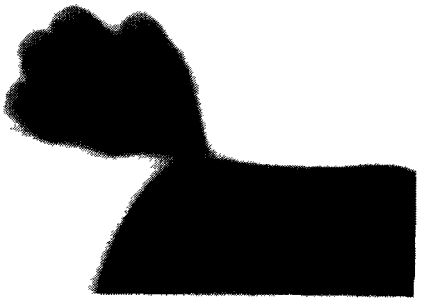
Better Care, Better Lives

Heart Attack
Type 2 Diabetes
Stroke
Breast Cancer

Introduction

The value to patients and society of better health care has been far greater than the increased investment in health care services over the past few decades, according to evidence from a variety of sources presented in this report. The value gained from expenditures on health care services is measured in this report as:

- *Health benefits*—such as life-years gained and deaths avoided;
- *Monetized health benefits*—calculated by applying a dollar value to a life-year gained or death avoided; and
- *Indirect benefits*—such as productivity.



This brochure summarizes the expenditures and associated health benefits for four diseases: heart attack, type 2 diabetes, stroke, and breast cancer. These diseases were chosen based on several factors:

- Each is a common condition in the U.S.
- Each condition can result in high disability and death rates.
- Virtually everyone in the U.S. is at risk for one or more of these diseases across most major demographic groups (gender, race, and to a lesser degree, age).
- Effective health care management practices and technological and drug innovations have improved outcomes for these particular diseases.
- Major financial investments have been made in these diseases, but the return to society of these investments has not been documented systematically.

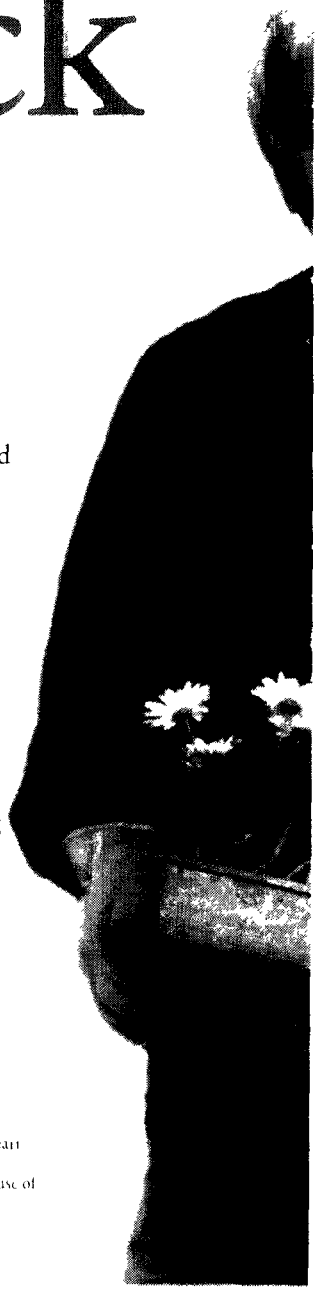
To comprehend our findings fully, it is important to understand several issues and caveats that framed our research:

- We attempted to evaluate the value of investment in health care by considering that significant advances are composed of many innovations including pharmaceuticals, medical devices, surgical techniques, and diagnostic technologies.
- We researched the existing clinical, economic, technology assessment and outcomes literature; consulted with clinical specialists in each of the four chosen conditions; and examined in detail the Medicare claims database and long-term care survey data.
- We specifically examined whether the incremental investment in health care has yielded a positive return. We did not attempt to address whether society could achieve these same health benefits at a lower cost or whether the health care system is operating efficiently as a whole.

This report provides additional perspective as the nation debates health care cost containment strategies, helping to refocus attention on the increasing value of health care investment. For additional information or to review the complete report, *The Value of Investment in Health Care*, please visit the MEDTAP® International, Inc. website at www.MEDTAP.com.

The dramatic reduction of disease and death due to heart attacks is one of the great achievements in medicine over the past few decades. Each year in the U.S., about 1.5 million people suffer a heart attack, with 2.6% of all people having suffered a heart attack at some point in their lives (American Heart Association 2003). Cardiovascular disease, of which heart attacks are a serious consequence, continues to be the leading cause of death and disability in the U.S., but recent advances in treatment have improved survival significantly.[1]

Heart Attack



Innovations Have Transformed Care for People Suffering from Heart Attacks

From 1970 to 2000, major advances have been made in the treatment and management of heart attack. Today, it is well-documented that an acute heart attack is due to plaque deposits and clotting that obstruct coronary arteries; the sooner the artery is opened, the more likely a patient is to survive with minimal damage to the heart muscle. Major innovations are summarized below, with specific innovations and their outcomes outlined in Table 1:

- Improvements in drug therapy (e.g., thrombolytics or "clot-busters" that break up clots, antiplatelet drugs that help prevent clot formation, cholesterol-lowering and blood pressure-lowering drugs to prevent heart attacks);
- Advances in surgical techniques and devices that are minimally invasive and more effective (e.g., a procedure called percutaneous transluminal coronary angioplasty that reopens blocked/narrowed arteries with a balloon inserted through a catheter and the use of tiny wire mesh devices called stents to keep blood vessels open);
- Advances in diagnostic technologies (e.g., electrocardiograms and diagnostic imaging that help diagnose heart attacks more quickly).

1 While beyond the scope of this study, it is important to note that significant progress also has been made in the *prevention* of first heart attacks. Identification of important risk factors (diabetes, obesity, smoking, etc.), new blood tests, increased knowledge of lifestyle's impact on cardiovascular disease, drug therapy with cholesterol- and blood pressure-lowering medications, and, when appropriate, use of elective procedures, have all contributed to an important reduction in first heart attacks.

Table 1 ■ History of Innovations in Heart Attack Treatment (1970 to 2000)

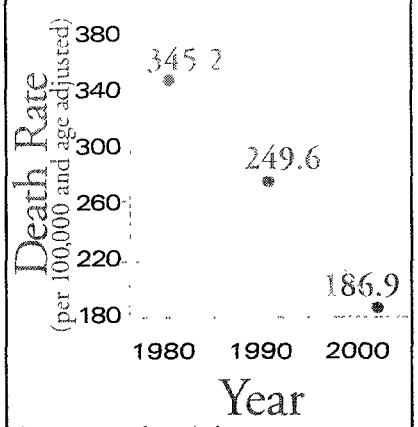
Innovation	Outcome
Cardiac care units first introduced	Allows faster response to heart attack patients
Use of coronary artery bypass graft (CABG) for revascularization increases	Increases long-term survival
Beta-blocker use in first hours of heart attack more prevalent	Reduces incidence of recurrent heart attacks
Lidocaine used to manage ventricular arrhythmias that occur after a heart attack	Improves 30-day survival
Streptokinase demonstrates effectiveness as clot-busting agent	Improves 30-day survival
Blood-thinners used in the first 7 days following initial heart attack	Reduces incidence of recurrent heart attacks
Beta-blocker use evolves from short-term to maintenance therapy	Improves long-term survival
Angioplasty introduced for revascularization for heart attack patients after they stabilize	Improves long-term survival
New thrombolytic, recombinant tissue-type plasminogen activator (rt-PA), introduced, which demonstrates effectiveness as clot-busting agent	Improves 30-day survival and leads to fewer bleeding complications
Ticlopidine and clopidogrel introduced as short-term antiplatelet therapy	Reduces need for invasive procedures (e.g., CABG) in long term
Primary angioplasty implemented for revascularization in acute period following heart attacks	Improves short- and long-term survival
Implantable cardiac defibrillators (ICDs) used electively in eligible patients who suffer from irregular heartbeats	Prevents recurrent heart attacks and sudden cardiac deaths
Bare-metal stents used for primary angioplasty procedures	Minimizes occurrence of restenosis
Cardiac troponin immunoassay tests introduced	Enables more specific and sensitive diagnosis
Drug-eluting (coated) stents (not specifically for heart attack patients but part of percutaneous coronary interventions [PCIs] to treat heart disease) introduced to keep blocked arteries open	Reduces rates of restenosis and repeat operations, improving long-term survival
Intravenous glycoprotein inhibitors used more frequently during primary angioplasty	Protects against thrombosis
Statin and anti-hypertensive therapy recommended to reduce risks causing heart attacks	Reduces occurrence of heart attacks
Eplerenone approved (first in new class of drugs known to selectively block aldosterone receptors)	Shown in one large clinical trial to improve survival of heart attack patients with congestive heart failure

Sources: Published literature and expert opinion

Health Outcomes Have Improved for Heart Attack Patients

From 1980 to 2000, the overall mortality rate for heart attacks declined by 46% from 345.2 to 186.9 per 100,000 persons (www.cdc.gov/nchs) (Figure 1), with the chance of dying within 30 days of a heart attack declining from 24.3% to 13.0% during this same period. Other clinical benefits and improvements in health outcomes realized from key advances are summarized below.

Figure 1 Decline in Death Rates for Heart Attack, 1980-2000



Source: www.cdc.gov/nchs

For Medicare Heart Attack Patients, Each Additional Dollar Spent on Care has Produced Health Gains Valued at $1.10

An analysis of Medicare claims data conducted for this report compared the five-year costs and health benefits (e.g., increased life expectancy) for Medicare heart attack patients in 1985-1989 to those in 1995-1999. As shown below, every additional dollar invested in the treatment of Medicare heart attack patients yielded a gain of $1.10.[2]

Outcomes for Heart Attack Patients

Measure	Outcome	Source
Mortality		
Overall mortality *(per 100,000, age-adjusted to the 2000 U.S. standard)*	Declined from 345.2 (1980) to 186.9 (2000)	www.cdc.gov/nchs
Risk of one-year mortality for heart attack survivors treated with antihypertensive therapy vs. usual care	Reduction ranged from 19% (ACEIs) to 22% (beta-blockers)	Pfeffer et al. 1992 Phillips et al. 2000
Risk of fatal heart disease or recurrent heart attack for heart attack survivors treated with long-term statin therapy vs. usual care	Declined by 24%	Sacks et al. 1996
Risks of death, recurrent heart attack, or revascularization for heart attack survivors treated with glycoprotein inhibitors	Declined by 48% to 52%	Sabatine & Jang 2000
30-day mortality		
Overall 30-day mortality rate	Declined from 24.3% (1980) 13.0% (1990)	www.cdc.gov/nchs
30-day mortality rate due to rt-PA vs. alternative drug therapy	Reduction of 15%	GUSTO 1993
Other measures		
Combined occurrence of six-month mortality and nonfatal recurrent heart attacks for heart attack survivors treated with primary angioplasty or thrombolytics[3]	8.5% (primary angioplasty), 16.8% (thrombolytics)	Grines et al. 1993
	7.2% (primary angioplasty), 11.9% thrombolytics)	Weaver et al. 1997

Incidence of six month mortality and nonfatal recurrent heart attacks lower with primary angioplasty in both studies

Costs and Outcomes for Medicare Heart Attack Patients

Measure (per patient)	Cost or Benefits
Increase in five-year costs (Medicare plus out-of-pocket)	$26,093
Average value of increased life expectancy (0.30 years or 12%)[2]	$28,632
Net Benefit in Dollars[2] *or*	$2,539
Benefit per Dollar Invested[2]	$1.10

2 These benefits represent estimates based on standard values for health gains: value of $100,000 per life year gained without an activity limitation, $50,000 per life year gained with an activity limitation, and $2,500 decrease per life year for each cognitive question answered incorrectly.

3 Studies vary in particular group studied e.g., different age groups, newly diagnosed vs. previously diagnosed, those with particular co-morbidities, etc. Additional details regarding inclusion criteria for the studies used to calculate VOI can be found in Appendix D of the full report.

4 Note that both an additional life year gained or additional quality adjusted life year (QALY) gained are valued at $100,000 (if the study did not discount costs and benefits) or $173,000 (if discounting was used) in order to generate these estimates.

For a list of references used for this summary brochure, please view the full report,

Research Documents the Value of Specific Investments in Heart Attack Care

Based on published literature,[3] health gains associated with specific investments in heart attack treatment are valued at $1.42 to $38.44 for each additional dollar spent,[4] as described below.

For every dollar invested in...	the value of health gains achieved has been...	Source
Routine therapy with beta-blockers vs. under-use of beta-blockers in heart attack survivors	$38.44	Phillips et al. 2000
Routine therapy with beta-blockers vs. usual care for heart attack survivors who are treated according to risk level	$6.49 (lowest risk) to $35.16 (highest risk)	Goldman et al. 1998
Mobile coronary care unit vs. usual care in the immediate treatment of heart attack	$10.00	Cretin 1977
Statin therapy vs. usual care for heart attack survivors with average cholesterol levels	$4 72 to $9.44	Tsevat et al. 2001
Coronary angiography to advise treatment plan vs. treatment initiation without angiography for patients with strongly positive exercise tolerance test or prior heart attack	$2.62 to $8.19	Kuntz et al 1996
rt-PA vs. alternative drug therapy for heart attack survivors treated with "clot-busting" drugs	$4.00	Mark et al. 1995
Angioplasty + stenting vs. angioplasty alone for patients experiencing a heart attack	$1 42	Cohen et al 2001
Preventive use of ICDs vs. amiodarone in patients with history of heart attack but no sustained ventricular arrhythmia	Possible gains (up to $2.41) or losses, depending on assumptions	Sanders 2001

Since the 1970s, Care for Heart Attack Patients has Advanced Dramatically

Advances in drugs and health care technologies since the 1970s have led to dramatic reductions in the risk of recurrent heart attacks and similarly dramatic reductions in the death rates due to heart attacks. Continued investment in drugs and health care technology are expected to yield further improvements.

In the 1970s...	Today.
patients admitted with an acute heart attack were hospitalized for five to seven days in a critical care unit followed by an additional three to four weeks in an open ward.	.heart attack patients face much shorter total hospitalizations, ranging on average from five to seven days
..fewer drug options were available to restore blood flow to the heart.	.. newer, safer thrombolytics are available for blood flow restoration.
...angioplasty was not available	...primary (used for immediate treatment of heart attack patients) and conventional (used in stable heart attack patients) angioplasty are used routinely to improve short- and long-term survival.
. tiny wire mesh devices called stents were not available.	. bare-metal stents have been added to primary angioplasty procedures to keep arteries open and minimize restenosis. .. drug-eluting stents (not specific to heart attack patients but used in heart disease patients) reduce artery re-blockage, improving long-term survival and minimizing hospitalizations.
. .antiplatelet therapy to prevent clot formation was limited to aspirin.	...the short-term use of new antiplatelets reduces mortality compared with aspirin alone.
..ICDs were not available.	...ICDs can be implanted percutaneously to regulate irregular heartbeats, often associated with prior heart attacks, and reduce the risk of sudden cardiac death
...physical activity for heart attack patients was strictly limited and included complete bed rest in the initial one to two weeks.	. rehabilitation is started sooner with patients encouraged to walk within the first few days and to begin supervised exercise within the first few weeks following a heart attack.
...risk factors were only beginning to be understood and addressed.	..prevention is emphasized and key risk factors such as diabetes, obesity, and smoking are better understood and routinely managed. Today, a constellation of drug therapies are used to reduce various risks antiplatelet therapy to prevent clot formation, antihypertensive agents to lower blood pressure, and statins to reduce cholesterol levels.
.extensive diagnostic imaging was not available.	. .numerous options for imaging and diagnostic procedures (e.g., ultrasound and cardiac catheterization) exist and provide key information on heart function and heart attack diagnosis, thereby helping treatment plans and improving outcomes.

Type 2 diabetes (also known as non-insulin-dependent diabetes mellitus) is the most common form of diabetes, affecting approximately 17 million individuals in the U.S., or 6% of the U.S. population (American Diabetes Association 2003). Unfortunately, poorly managed diabetes can result in long-term complications such as diseases of the eye, kidney, nervous system, and cardiovascular system. Such complications can lead to blindness, kidney failure, nerve damage, heart attack, stroke, and death. These complications not only reduce the length and quality of life for people with type 2 diabetes but also dramatically increase the medical costs associated with the disease.

Type 2 Diabete

Innovations Have Transformed Care for People Suffering from Type 2 Diabetes

Although type 2 diabetes cannot yet be cured, it can be managed very effectively. The numerous advances (Table 2) made over the past few decades have significantly changed how type 2 diabetes is managed today; these advances are further expected to decrease the incidence and costs of long-term complications. These advances primarily include improved diagnostic and monitoring techniques (e.g., hemoglobin A1c tests that measure blood glucose levels, self-monitoring blood glucose kits), improvements in oral therapy and insulin injections, and widespread recognition of the relationship of type 2 diabetes to elevated cholesterol levels and high blood pressure – and the need to treat these associated conditions.

Table 2 ■ History of Innovations in the Treatment of Type 2 Diabetes (1970 to 2000)

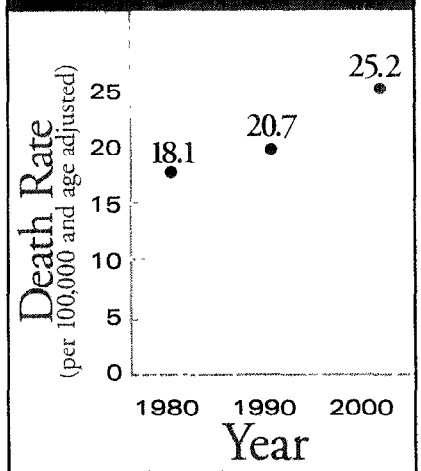
	Innovation	Outcome
1970s	Two classes of medications available: insulin (injected), sulfonylureas (oral)	Used in addition to diet and exercise to improve outcomes of type 2 diabetes patients
	Self-monitoring blood glucose levels introduced	Allows patients to track glucose levels more closely, revolutionizing diabetes management
	Hemoglobin A1c lab test created	Improves doctors' ability to monitor blood glucose levels
1980s	Better devices introduced for self-monitoring blood glucose levels	Enables more accurate glucose readings
	Two second-generation sulfonylureas (glyburide, glipizide) approved	Increases oral therapeutic options, allowing more patients to be treated
	Photocoagulation therapy (laser surgery to prevent vision loss) and vitrectomy procedures (surgical removal of the gel-like substance at the eye's center) become widely used	Improves outcomes of diabetic eye disease
	Combination therapy becomes common alternative for individuals not controlled on single agent	Further increases therapeutic options and allows better management of diabetes
	Hemoglobin A1c lab test improves	Allows more accurate testing and better ability to predict likelihood of complications
1990s	Initial recognition that tight blood glucose control needed to manage type 2 diabetes effectively	Leads to better short- and long-term outcomes, potentially delaying the onset of diabetes-related complications
	Innovations occur in insulin therapy (human vs. recombinant DNA; short-acting vs. long-acting) and oral agents (biguanides, thiazolidinediones, alpha-glucosidase inhibitors)	Improves patient management and outcomes, allowing more patients to be treated successfully
	Awareness that tight control of blood pressure and cholesterol has beneficial effects on diabetes-related complications	Expected to lead to reductions in diabetes-related complications
2000s	Further improvements in devices for self-monitoring blood glucose levels, including non-invasive options	Allows monitoring that is more accurate, convenient, and less painful
	Combination therapy for oral agents offered as one pill	Compliance with therapy expected to increase
	First drug in a new class of drugs (D-phenylalanine derivatives) approved	Offers new alternative for patients with uncontrolled glucose levels

Sources: Published literature and expert opinion

Health Outcomes Have Improved for Type 2 Diabetes Patients

The increasing incidence of obesity in the U.S. has led to an increasing incidence of type 2 diabetes. Overall mortality rates for diabetes mellitus have steadily increased over the past 20 years from 18.1 to 25.2 per 100,000 persons, given the increase in incidence of type 2 diabetes (Figure 2) (www.cdc.gov/nchs).▲ However, research suggests that prevention and better management of the disease, made possible by recent advances in drugs and health care technologies, result in better clinical outcomes and lower complication rates.[5] These outcomes are summarized below.

Figure 2 Increase in Death Rates for Diabetes Mellitus, 1980-2000▲



Source: www.cdc.gov/nchs

For Medicare Type 2 Diabetes Patients, Each Additional Dollar Spent on Care has Produced Health Gains Valued at $1.49

An analysis of Medicare claims data conducted for this report compared the five-year costs and health benefits (e.g., increased life expectancy) for Medicare type 2 diabetes patients in 1985-1989 to those in 1995-1999. As shown below, every additional dollar invested in the treatment of Medicare type 2 diabetes patients yielded a gain of $1.49.[6]

Outcomes for Type 2 Diabetes Patients

Measure	Outcome	Source
Diabetes-related complications		
Combined occurrence of diabetic retinopathy, neuropathy, and nephropathy when blood glucose levels are tightly controlled* among type 2 diabetes patients	Declined by 25%	UKPDS 1998a
Combined occurrence of diabetic retinopathy, neuropathy, and nephropathy when blood pressure is tightly controlled† among type 2 diabetes patients	Declined by 37%	UKPDS 1998b
Occurrence of any diabetes complication when blood pressure is tightly controlled† among type 2 diabetes patients	Declined by 24%	UKPDS 1998b
Occurrence of stroke when blood pressure is tightly controlled† among type 2 diabetes patients	Declined by 44%	UKPDS 1998b
Occurrence of heart failure when blood pressure is tightly controlled† among type 2 diabetes patients	Declined by 56%	UKPDS 1998b
Mortality		
Occurrence of diabetes-related deaths when blood glucose levels are tightly controlled* among type 2 diabetes patients	Declined by 10%	UKPDS 1998a
Occurrence of diabetes related deaths when blood pressure is tightly controlled† among type 2 diabetes patients	Declined by 32%	UKPDS 1998b
Occurrence of deaths due to any cause when blood glucose levels are tightly controlled* among type 2 diabetes patients	Declined by 6%	UKPDS 1998a
Occurrence of fatal and nonfatal heart attacks when blood glucose levels are tightly controlled* among type 2 diabetes patients	Declined by 18%	UKPDS 1998a
Other		
Risk of coronary events when cholesterol levels lowered to 170 mg/dl with statin therapy	Declined by 25%	Goldberg et al 1998
Reduced incidence of severe vision loss among patients whose diabetic retinopathy is detected and treated early	Declined by 84%	Ferris 1993
Gains in employment when type 2 diabetes well-managed with drug therapy vs. no drug therapy	Remain employed 97% vs 85%, More productive on the job 99% vs 87%	Testa & Simonson 1998

Costs and Outcomes for Medicare Type 2 Diabetes Patients

Measure (per patient)	Cost or Benefits
Increase in five-year costs (Medicare plus out-of-pocket)	$11,337
Average value of increased life expectancy (0.25 years or 7%)[6]	$16,930
Net Benefit in Dollars[6] *or*	$5,593
Benefit per Dollar Invested[6]	$1.49

5 While these clinical trial findings are too recent to be observed in "real-world" settings, they are critical in helping us understand the importance of managing risk factors for type 2 diabetes

6 These benefits represent estimates based on standard values for health gains: value of $100,000 per life year gained without an activity limitation, $50,000 per life year gained with an activity limitation, and $2,500 decrease per life year for each cognitive question answered incorrectly

▲ Mortality statistics from the CDC do not distinguish between type 1 and type 2 diabetes. However, 90% of all diabetes diagnoses are for type 2 diabetes, suggesting most of the diabetes-related deaths are most likely due to type 2

* Tight control of blood glucose levels defined as maintaining hemoglobin A1c levels at 7.0% vs 7.9%

† Tight blood pressure control defined as maintaining blood pressure below 150/85 mmHg

For a list of references used for this summary brochure, please view the full report,

Research Documents the Value of Specific Investments in Type 2 Diabetes Care

Based on published literature described below,[7] health gains associated with specific investments in the treatment of type 2 diabetes are valued at $3 to $36 for each additional dollar spent.[8]

For every dollar invested in...	the value of health gains achieved has been...	Source
Screening and treatment of diabetic retinopathy vs. no screening for insulin-users	$36.00	Javitt and Aiello 1996
Treatment with ACE inhibitors for all newly diagnosed type 2 diabetics vs. treatment with ACE inhibitors for newly diagnosed type 2 diabetics who have elevated urinary protein levels (microalbuminuria or gross proteinuria)	$21.36	Golan et al 1999
Tight blood glucose control to target level vs. less stringent control in newly diagnosed type 2 diabetics	$8.65	Eastman et al. 1997
Treatment with statin vs. no statin treatment for type 2 diabetics with cardiovascular disease	$7.00 to $31.00	Grover et al. 2001
Tight vs. less stringent blood glucose control in newly diagnosed type 2 diabetics	$3.77	CDC 2002
Tight vs. less stringent control of cholesterol levels in newly diagnosed type 2 diabetics	$3.00	CDC 2002
Tight vs. less stringent blood pressure control in newly diagnosed type 2 diabetics	Savings in overall treatment costs, as well as health gains	CDC 2002
Tight vs less stringent blood pressure control in elderly type 2 diabetics with high blood pressure	Savings in overall treatment costs, as well as health gains	Elliott et al. 2000

Since the 1970s, a Better Understanding of Type 2 Diabetes and Advances in Care have Improved the Outlook

Advances in drugs and health care technologies since the 1970s have led to better management of type 2 diabetes patients. Many of the more recent gains in our understanding of effectively managing type 2 diabetes are expected to lead to significant long-term improvements in diabetes-related complications.

In the 1970s...	Today...
..diabetes was classified as juvenile and adult-onset, with the role of insulin resistance (insulin-dependent, non-insulin dependent) recognized only in the late 1970s.	. the distinction between type 1 and type 2 diabetes has been documented. The risk of obese adolescents developing type 2 diabetes (originally known as adult-onset) is now recognized.
...the roles of obesity and lack of exercise in adult-onset diabetes were only touched upon in patient management.	..the roles of obesity and lack of exercise are emphasized much more strongly.
. .the hemoglobin A1c lab test had just been introduced. While it improved a doctor's ability to monitor blood glucose levels, it did not always provide accurate readings.	hemoglobin A1c tests have significantly progressed, allowing for more accurate blood glucose readings, better prediction of diabetes-related complications, and overall better management and quality of life for patients living with diabetes.
...oral drug treatment consisted almost exclusively of sulfonylureas, but fear of cardiovascular side effects inhibited their widespread use.	. .safer sulfonylureas are available, along with several other classes of oral agents (biguanides, thiazolidinediones, and alpha-glucosidase inhibitors)
...insulin therapy was limited to short-acting agents with inconvenient dosing schedules (e.g., before every meal and every night before bedtime)	. options include long-acting insulin with better dosing schedules, potentially leading to better patient compliance with therapy and more effective insulin made with recombinant DNA
.. technologies to improve monitoring of glucose levels had just been developed.	...physician and patient monitoring of blood glucose levels is far more accurate In addition, advances in home glucose monitoring kits and hemoglobin A1c tests make self and physician monitoring of glucose levels more convenient and less painful. For example, newer, non-invasive tests can check blood glucose levels without puncturing the skin
...little was known about the importance of controlling factors other than blood glucose.	...extensive research has highlighted the importance of controlling blood pressure and cholesterol levels, in addition to blood glucose. Treatment based on this understanding is expected to reduce long-term complications.
...patients suffering from complications had limited treatment options.	. laser surgery and vitrectomy procedures are used to treat diabetic eye disease, while dialysis and transplant surgery help improve quality of life for diabetics with kidney disease.

7 Studies vary in particular group studied, e g , different age groups, newly diagnosed vs. previously diagnosed, those with particular co-morbidities, etc Additional details regarding inclusion criteria for the studies used to calculate VOI can be found in Appendix D of the full report.

8 Note that both an additional life year gained or additional quality adjusted life year (QALY) gained are valued at $100,000 (if the study did not discount costs and benefits) or $173,000 (if discounting was used) in order to generate these estimates

Stroke is the third leading cause of death in the U.S. and the leading cause of adult disability; roughly 1.6% of the U.S. population has suffered a stroke. Two-thirds of stroke survivors suffer from significant long-term physical and emotional disabilities. The condition and associated disabilities cost the U.S. $30-40 billion a year. Given the impact of stroke on victims and their families, progress in prevention, diagnosis, and treatment is critical.

Stroke

Innovations Have Transformed Care for People Suffering from Strokes

Today, it is well-understood that the faster a stroke is diagnosed (with better vascular and brain imaging) and treatment initiated (with "clot-busting" and plaque-removing therapy), the lower the chances are of long-term disability. Key advances in the prevention and treatment of stroke between 1970 and 2000 are summarized briefly below, with details of specific innovations and their outcomes outlined in Table 3:

- Development of safer, more effective "clot-busting" agents to prevent and reduce the occurrence of blood clot formation. The 2003 American Stroke Association practice guidelines recommend immediate intravenous administration of rt-PA, the only drug therapy approved in the U.S. for the treatment of ischemic stroke;
- Advent of carotid endarterectomy, a procedure that removes plaque in the carotid arteries of the neck and helps prevent stroke;
- Better-tolerated and more effective drugs for controlling high blood pressure and cholesterol; and
- Improvements in brain imaging, including scans and weighted imaging, vascular imaging, such as ultrasonography, magnetic resonance angiography [MRA], and transthoracic and transesophageal echocardiography.

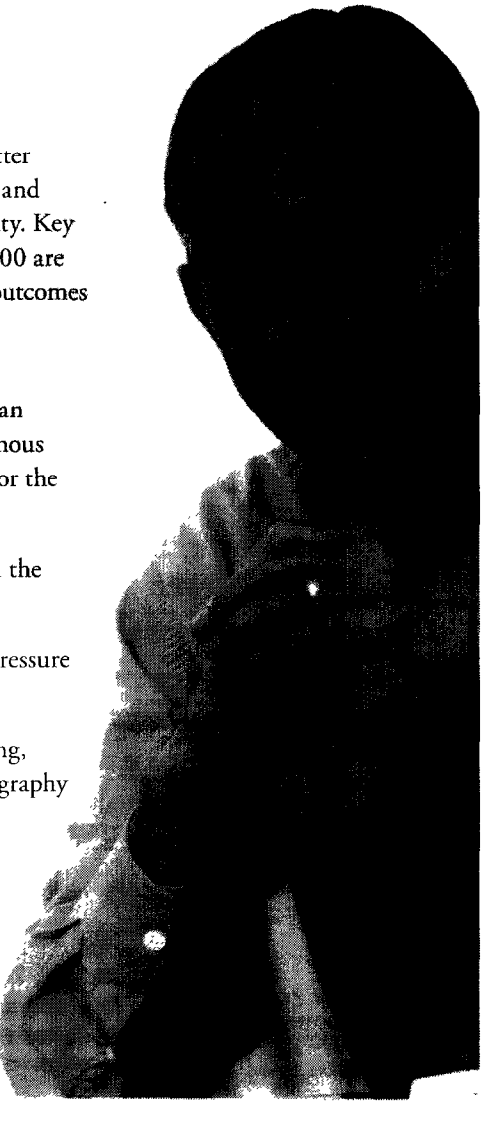


Table 3 ■ History of Innovation in the Treatment of Stroke (1970 to 2000)

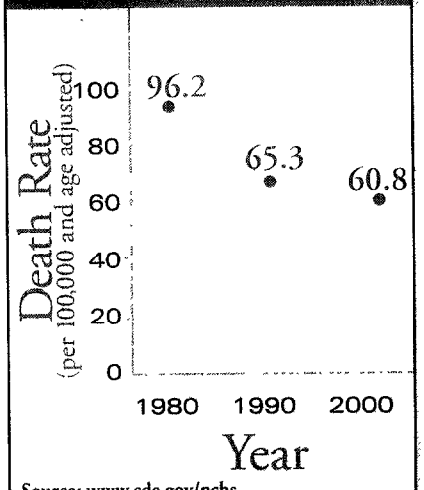
	Innovation	Outcome
1970s	Aspirin shown to be effective in treating stroke	Improves short- and long-term survival
	CT and PET scanning developed	Allows clinicians to distinguish type of stroke (ischemic vs. hemorrhagic), which enables more targeted treatment
1980s	Early surgery for aneurysm initially used	Improves survival for patients with hemorrhagic stroke
	MRI developed	Further improves diagnosis and evaluation of stroke patients
	"Clot-busting" therapy shows promise in stroke patients	Improves short-term survival of stroke patients
	Acute rehabilitation gains popularity and becomes routinely used	Offers an important option for functional recovery of stroke patients
1990s	Carotid endarterectomy proven effective in preventing stroke among high-risk patients with severe narrowing of carotid (neck) arteries	Lowers risk of stroke in high-risk patients
	Anticoagulants shown to be effective in preventing stroke in people with atrial fibrillation	Lowers risk of stroke in high-risk patients
	Combination product (aspirin + dipyridamole) approved to reduce the risk of recurrent stroke in people suffering transient ischemic attack or ischemic stroke	Lowers risk of stroke in high-risk patients
	Heightened awareness of need to control blood pressure and cholesterol	Expected to prevent recurrent stroke in patients suffering prior stroke or other coronary illness
	rt-PA becomes routinely used in the first three hours of a stroke	Improves short-term survival in stroke patients
	Brain imaging (e.g., CT and PET scans; diffusion- and perfusion-weighted imaging) improves significantly	Helps diagnose strokes and their underlying causes and helps identify patients at risk for strokes
	Glycoprotein inhibitors approved to reduce risk of coronary events in patients suffering a stroke or other coronary event	Lowers risk of stroke in high-risk patients
	Microcoils introduced as effective, minimally invasive treatment for brain aneurysms to prevent rupture and possible stroke	Prevents stroke with minimal patient discomfort
	Subacute rehabilitation introduced and becomes more popular than acute rehabilitation	Becomes another, less expensive option in functional recovery of stroke patients
2000s	Use of vascular imaging (ultrasonography, MRA, single-photon emission computed tomography [SPECT], and transthoracic and transesophageal echocardiography) increases	Helps diagnose strokes and identify at-risk patients faster and more accurately
	Fiber optic endoscopy introduced to evaluate swallowing and laryngeal function, becoming integral to stroke care	Helps identify obstructed swallowing, thereby minimizing occurrence of stroke-related pneumonia
	Losartan approved for a new use to reduce risk of stroke in patients with high blood pressure and left ventricular hypertrophy	Expected to minimize occurrence of stroke in these patients

Sources: Adapted from http://www.americanstroke.org and published literature

Health Outcomes Have Improved for Stroke Patients

Between 1980 and 2000, the mortality rate for strokes declined by 37% (www.cdc.gov/nchs) (Figure 3). The literature documents how improvements in management of stroke patients and better prevention of first and recurrent strokes have contributed to better outcomes as summarized below.

Figure 3 Decline in Death Rates for Stroke, 1980-2000



Source: www.cdc.gov/nchs

For Medicare Stroke Patients, Each Additional Dollar Spent on Care has Produced Health Gains Valued at $1.55

An analysis of Medicare claims data conducted for this report compared the five-year costs and health benefits (e.g., increased life expectancy) for Medicare stroke patients in 1985-1989 to those in 1995-1999. As shown below, every additional dollar invested in the treatment of Medicare stroke patients yielded a gain of $1.55.[9]

Outcomes for Stroke Patients

Measure	Outcome	Source
Impact of immediate treatment with rt-PA on stroke-related disability	At least 30% more likely to have minimal or no disability at three months when treated with rt-PA	NINDS 1995
Risk of stroke when ticlopidine vs aspirin used in high-risk patients suffering prior transient ischemic attack or minor stroke	Declined by 21%	Hass et al. 1989
Combined risk of ischemic stroke, heart attack, and vascular death when clopidogrel vs aspirin used in high-risk patients suffering an atherosclerotic vascular event	Declined by 8.7%	CAPRIE 1996
Prevention of recurrent stroke when carotid endarterectomy used in eligible patients with blocked carotid (neck) arteries who suffered a transient ischemic attack	Increases average quality-adjusted life expectancy by 13.8 months vs no therapy and by 11.2 months vs aspirin	Nussbaum et al 1996

Costs and Outcomes for Medicare Stroke Patients

Measure (per patient)	Costs or Benefits
Increase in five-year costs (Medicare plus out-of-pocket)	$16,035
Average value of increased life expectancy (0.21 years or 10%)	$24,903
Net Benefit in Dollars[9] *or*	$8,868
Benefit per Dollar Invested[9]	$1.55

9 These benefits represent estimates based on standard values for health gains: value of $100,000 per life year gained without an activity limitation, $50,000 per life year gained with an activity limitation, and $2,500 decrease per life year for each cognitive question answered incorrectly.

For a list of references used for this summary brochure, please view the full report,

Research Documents the Value of Specific Investments in Stroke Prevention and Care

Published literature[10] suggests that specific investments in stroke prevention and treatment have been cost-effective, with the value of health gains ranging from savings in overall treatment costs to a value of $2 to $6 per additional dollar invested, as shown below:[11]

For every dollar invested in...	the value of health gains achieved has been...	Source
Ticlopidine vs. aspirin to prevent strokes in patients who suffered a transient ischemic attack, reversible ischemic neurological deficit, amaurosis fugax, or minor stroke	$2 to $4	Oster et al 1994
Clopidogrel vs. aspirin to prevent recurrent strokes in patients suffering first strokes	$6	Sarasin et al 2000
rt-PA vs. no therapy in the first three hours following stroke for *treatment* of stroke	Savings in overall treatment costs, as well as health gains	Fagan et al 1998
Carotid endarterectomy (CEA) vs. aspirin in patients who suffered a transient ischemic attack (to prevent subsequent stroke)	Savings in overall treatment costs, as well as health gains	Nussbaum et al 1996

Since the 1970s, Significant Advances in Prevention, Diagnosis, and Treatment Have Reduced the Death and Disability Associated with Stroke

Advances in drugs and health care technologies since the 1970s have led to better diagnosis and management of stroke patients, as well as improved prevention of recurrent stroke in high-risk patients. Continued investment in drugs and health care technology are expected to continue to lead to fewer stroke-related disabilities and deaths.

In the 1970s...	Today...
...patients were less likely to recognize the symptoms of stroke, which likely delayed arrival at the hospital.	awareness of stroke symptoms and the importance of immediate treatment has grown.
...once reaching the hospital, patients might have waited several hours before being seen, and no specific interventions (besides general care) were undertaken.	. using rt-PA immediately following stroke has resulted in improved morbidity: patients are more likely to have minimal or even no disability following a stroke.
..aspirin was one of the few drugs available to prevent stroke.	...antiplatelets (in combination with aspirin) are routinely used in the short-term to prevent recurrent stroke and other coronary events, showing better effectiveness than aspirin alone. ...glycoprotein inhibitors, approved for stroke patients in the 1990s, are routinely used to reduce the risk of coronary events in stroke patients, yielding significant improvements in outcomes.
...few options for brain imaging were available	...options have grown (e.g., diffusion- and perfusion-weighted imaging, CT and PET scans), allowing for faster diagnosis and subsequent treatment of stroke.
...rudimentary echocardiography was available but not widely used, given its images were not high quality.	. .numerous technologies (MRA, SPECT, ultrasonography, transesophageal and transthoracic echocardiography) are available and provide high-resolution images of the brain and vascular system, enabling faster diagnosis and treatment.
. .it was typical for patients to be discharged to nursing homes following strokes.	...acute and subacute rehabilitation facilities exist, with patients being discharged much sooner to these facilities
...surgical options for stroke prevention were limited.	...carotid endarterectomy can potentially be used to prevent stroke among eligible patients with severe narrowing of carotid (neck) arteries ...microcoil devices provide effective, minimally invasive treatment for brain aneurysms and help prevent stroke
..speech and physical therapy interventions were delayed until discharge to a suitable care facility.	...these interventions begin much earlier, often during the initial hospitalization.

10 Studies vary in particular group studied e g , different age groups, newly diagnosed vs previously diagnosed, those with particular co-morbidities, etc Additional details regarding inclusion criteria for the studies used to calculate VOI can be found in Appendix D of the full report

11 Note that both an additional life year gained or additional quality adjusted life year (QALY) gained are valued at $100,000 (if the study did not discount costs and benefits) or $173,000 (if discounting was used) in order to generate these estimates

Breast cancer is one of the most commonly diagnosed cancers among women, affecting 2.2 million women out of a total of 143.4 million women in the U.S. in 2000 (SEER 2002). About 40% of these women have lived with breast cancer for 10 or more years. In 2001 alone, an estimated 192,000 new cases of invasive breast cancer were diagnosed. While substantial progress has been made in diagnosing and treating breast cancer, researchers continue their efforts to improve the outcomes for women affected by this disease.

Breast Cancer

Innovations Have Transformed Care for Women Suffering from Breast Cancer

From 1970 to 2000, the most critical advances in the treatment of breast cancer include: better diagnostic techniques and imaging; less toxic and more effective chemotherapy; less invasive surgical procedures with more cosmetic appeal and better psychological outcomes; and new hormonal regimens that prevent or delay the cancer from spreading. These innovations, as well as many others, are discussed in Table 4.

Table 4 ■ History of Innovation in Breast Cancer Treatment (1970 to 2000)

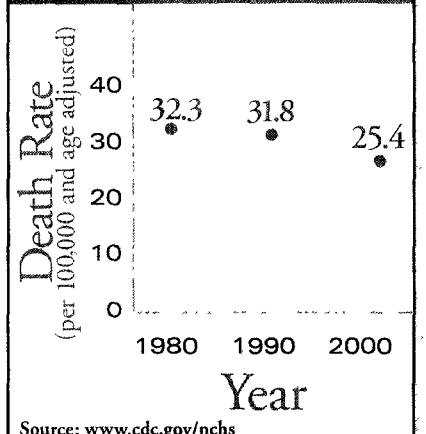
Innovation	Outcome
Tamoxifen becomes standard treatment	Demonstrates less toxicity than other anti-cancer drugs
Systematic mammography screening begins	Results in earlier diagnoses and treatment, contributing to a decline in breast cancer-related deaths
Combination chemotherapy after surgery and platinum-based chemotherapy introduced	Leads to improvements in disease-free survival
Modified radical mastectomy replaces radical mastectomy	Offers wider cosmetic appeal
NIH recommends breast conserving surgery as optimal treatment for most women with early stage breast cancer	Offers even better cosmetic outcomes over radical modified mastectomy
Breast reconstruction with the free TRAM flap introduced	Preserves the function of the abdominal musculature
Better tolerated hormonal therapies introduced	Enables more patients to be treated with safer outcomes
Stereotactic core needle biopsy introduced (minimally invasive procedure that uses a needle to remove tissue sample)	Eliminates scarring, stitches, anesthesia, hospitalization, while improving diagnostic accuracy
Digital spot view mammography introduced	Improves stereotactic biopsy accuracy
Sentinel lymph node biopsy introduced	Provides minimally invasive method of determining whether cancer has spread to lymph nodes
Trastuzumab shown to be effective therapy for women with certain metastatic tumors	Improves disease-free survival
Taxanes added to standard chemotherapy	Leads to improvements in disease-free survival rates
Computer-aided detection systems introduced for mammography	Improves detection of early stage malignancies
Advances in brachytherapy occur (type of radiation therapy where source of radiation is placed close to the body surface or within the body)	Reduces need for multiple needles inserted into breast, thereby minimizing risk of infection
Intensity-modulated radiation therapy introduced (delivers highest possible radiation dose to tumors while sparing surrounding healthy tissue)	Reduces likelihood of long-term toxicity
Tests for HER2 receptor genes designed	Offers improved accuracy in identifying high-risk breast cancers
Letrozole researched in older women initially treated with tamoxifen	Reduces recurrence of breast cancer

Sources: Published literature and expert opinion

Health Outcomes Have Improved for Women with Breast Cancer

Since the early 1990s, mortality rates for all stages of breast cancer and the risk of the cancer spreading (metastatic disease) have steadily decreased. From 1980-2000, the mortality rate for breast cancer declined by 21% (www.cdc.gov/nchs) (Figure 4), and the probability of living for five years or more after a diagnosis of breast cancer increased from 76.9% in 1980 to 86.6% in 1995 (www.nci.nih.gov; SEER 2000). In addition, adding chemotherapy to primary surgical treatment increases five-year survival rates by 33% (Abraham and Zujewski 2001). Additional survival benefits, specifically broken down by stage of breast cancer, are summarized below.

Figure 4 ■ Decline in Death Rates for Breast Cancer, 1980-2000



Source: www.cdc.gov/nchs

For Medicare Breast Cancer Patients, Each Additional Dollar Spent on Care has Produced Health Gains Valued at $4.80

An analysis of Medicare claims data conducted for this report compared the five-year costs and health benefits (e.g., increased life expectancy) for Medicare breast cancer patients in 1985-1989 to those in 1995-1999. As shown below, every additional dollar invested in the treatment of Medicare breast cancer patients yielded a gain of $4.80.[12]

Outcomes for Breast Cancer Patients

Measure	Outcome	Source
Mortality* *(per 100,000, age-adjusted to the 2000 U.S standard)*	Declined from 32.3 (1980-1984) to 31.8 (1990) to 25.4 (2000) www.cdc.gov/nchs	www.cdc.gov/nchs
5-year survival		
Overall	Improved from 76 9% (1980) to 86 6% (1995)	SEER 2003
Local Disease	Improved from 89.6% (1980) to 96.5% (1990) to 97 0% (1995)	www.nci.nih.gov
Regional Disease	Improved from 70 0% (1980) to 75 7% (1990) to 78 2% (2000)	www.nci nih.gov
Metastatic Disease	Improved from 18 7% (1980) to 24.4% (1990) to 22.2% (2000)	www nci nih.gov
Improvement due to adjuvant chemotherapy	Increased relative five-year survival rates by 33%	Abraham & Zujewski 2001
Risk of developing metastatic disease *(for a 54-year-old woman diagnosed with lymph node positive breast cancer)*	Declined from 40% to 15%	Abraham & Zujewski 2001

Costs and Outcomes for Medicare Breast Cancer Patients

Measure (per patient)	Costs or Benefits
Increase in five-year costs (Medicare plus out-of-pocket)	$4,676
Average value of increased life expectancy (0.32 years or 8%)	$22,341
Net Benefit in Dollars[12] *or*	$17,665
Benefit per Dollar Invested[12]	$4.80

12 These benefits represent estimates based on standard values for health gains value of $100,000 per life year gained without an activity limitation, $50,000 per life year gained with an activity limitation, and $2,500 decrease per life year for each cognitive question answered incorrectly

For a list of references used for this summary brochure, please view the full report,

Research Documents the Value of Specific Investments in the Treatment of Breast Cancer

Based on published literature,[13] health gains associated with specific investments in the treatment of breast cancer are valued at $1.12 to $36.81 for each additional dollar spent, as shown below:

For every dollar invested in...	the value of health gains achieved has been...	Source
Letrozole vs current standard of care for post-menopausal women with advanced breast cancer	$27.03 to $36.81	Karnon and Jones 2003
Breast Conserving Surgery vs Modified Radical Mastectomy for eligible women	$6.90	Palit et al 2000
Biennial mammography vs limited screening for eligible women ages 50-59	$5 30	Lindfors and Rosenquist 1995
Radiation therapy + surgery vs surgery alone for women with early stage breast cancer	$5 24	Hayman et al 1998
Biennial mammography for women ages 50-59 + annual mammography for ages 40-49 vs limited screening for women in either age group	$4.20	Lindfors and Rosenquist 1995
Mammography + stereotactic core needle biopsy vs observation only + surgical biopsy for eligible women	$3 70 to $4 83	Lindfors and Rosenquist 1994
Adjuvant chemotherapy vs. no chemotherapy, following primary surgery for pre-menopausal women	$3.27 to $7 31	Smith and Hillner 1993
Chemotherapy + primary surgery vs. surgery alone for elderly women with estrogen-receptor negative, stage 1 breast cancer	$2.44	Desch et al 1993
Tamoxifen + adjuvant chemotherapy vs. tamoxifen alone for post-menopausal women with node positive breast cancer	$1 86	Hillner and Smith 1992
Autologous bone marrow transplant following induction chemotherapy vs. standard chemotherapy for women with metastatic breast cancer	$1 12	Hillner et al. 1992

Since the 1970s, Advances in Treatment Have Led to Longer Lives and Better Psychological Outcomes for Women with Breast Cancer

Advances in drugs and health care technologies since the 1970s have led to longer, better lives for women with breast cancer, in addition to improvements in their quality of life. Favorable outcomes such as these are expected to grow as long as investments in drugs and health care technology continue.

In the 1970s...	Today...
..patients were hospitalized when they underwent chemotherapy.	more than 90% of chemotherapy is given on an outpatient basis.
. chemotherapy was poorly tolerated.	. .more effective medicines reduce nausea and vomiting associated with chemotherapy and preserve red and white blood cells, often depleted in chemotherapy.
...limited options for drug therapies existed	. .newer hormonal therapies (e.g., aromatase inhibitors) have become available and increase disease-free survival rates, have less toxicity, and improve quality of life . other new agents have led to an increase in cure rate (e.g., taxanes) and greatly improve outcomes for women with metastatic disease (e.g., trastuzumab)
...virtually all surgeons performed mastectomies with the option of reconstructive surgery rarely offered.	...breast conserving surgery is routinely offered and reconstructive surgery is often performed in conjunction with mastectomies
.preoperative counseling was often limited, with women expecting simple biopsies and waking up with extensive mastectomies.	. options are discussed prior to any surgery with informed consent
...radiation therapy to treat cancer postoperatively led to serious side effects, including high toxicity for surrounding normal tissues.	. .more sophisticated radiation therapy options are available, reducing toxicity to normal tissues, especially for women electing lumpectomy with postoperative radiation.
...lymph node dissection was frequently used, often leading to lymphedema (swelling of the arm).	.. sentinel lymph node biopsy is widely practiced, reducing the likelihood of ill effects seen with lymph node dissection.
.mammography was still in the early stages of innovation and was not in widespread use.	. better mammography techniques (e.g., high resolution digital mammography), as well as their increased use lead to early detection and continue to contribute to lower mortality
tamoxifen, a hormonal therapy which can improve five-year disease-free survival rates for eligible patients, was only in limited use	. tamoxifen is used regularly and can lead to substantial improvements in five-year disease-free survival.

13 Studies vary in particular group studied e g different age groups, newly diagnosed vs previously diagnosed, those with particular co-morbidities, etc Additional details regarding inclusion criteria for the studies used to calculate VOI can be found in Appendix D of the full report

Glossary

ACE Inhibitor (ACEI) – Class of drugs used to lower blood pressure by inhibiting angiotensin-converting enzymes (ACEs), which help the conversion of angiotensin to angiotensin II.

Adjuvant chemotherapy – Chemotherapy received in addition to the primary course of treatment.

Alpha-glucosidase inhibitors – Class of oral drugs used to treat diabetes by decreasing gastrointestinal carbohydrate absorption (delay absorption of carbohydrates from food and their digestion).

Amaurosis fugax – A short-lived episode of blindness in one eye.

Aneurysm – Localized widening/ballooning-out of a vessel, resulting in a "bulge" that can weaken the vessel's wall and rupture; may occur in the brain, increasing blood pressure and resulting in a stroke.

Angiography – X-ray procedure that takes pictures ("angiograms") of blood vessels. It is usually done by inserting a catheter into an artery or vein in the groin to evaluate blood flow.

Angioplasty – Procedure that re-opens blocked/narrowed arteries to the heart by using a catheter to insert a balloon in the blocked/narrowed portion of the artery; the balloon is then inflated to widen the artery. Also known as "percutaneous transluminal coronary angioplasty."

Angiotensin II Receptor Blocker (ARB) – Class of drugs used to lower blood pressure by blocking angiotensin (eventually converted to angiotensin II), which causes blood vessels to constrict, raising heart rate and blood pressure.

Anticoagulant – Class of drugs that inhibit blood clot formation; also known as "clot-busting" drugs.

Antiplatelet – Class of drugs that inhibit blood clot formation by keeping platelets (the body's natural blood-clotters) from binding together; also known as "clot-busting" drug.

Atherosclerotic vascular event – Any type of cardiovascular event that is due to the progressive narrowing and hardening of the arteries over time because of fatty build-up, which results in blocked arteries and blood clot formation. These events eventually lead to the atherosclerotic vascular event.

Beta-blocker – Class of drugs used to lower blood pressure by blocking beta receptors on the surface of heart cells.

Biguanide – Class of oral drugs used to treat diabetes by decreasing hepatic glucose release.

Cardiac catheterization – Process to examine the heart by inserting a thin tube/hollow needle (catheter) into a vein or artery and passing it into the heart, often to open blockages.

Carotid artery – Two large arteries in the front of the neck that provide blood to the brain. A stroke most often occurs when the carotid arteries become blocked and the brain does not get enough oxygen.

Carotid endarterectomy – Surgery to remove plaque build up in the carotid arteries.

Clopidogrel – Type of antiplatelet drug approved for use in the 1990s that minimizes risk of recurrent stroke .

Computed Tomography (CT) – Method of examining organs by scanning them with X-rays and then using a computer to construct an image based on the X-rays.

Coronary Artery Bypass Graft (CABG) – Procedure used to re-route blood supply around a blocked section of a coronary artery by removing healthy blood vessels from another part of the body (e.g., leg or chest wall) and surgically attaching these vessels to the diseased artery in such a way that blood flows around the blocked section.

Diabetic nephropathy – Kidney disease due to diabetes.

Diabetic neuropathy – Nerve disorders or damage due to diabetes.

Diabetic retinopathy – Disease of the retina that potentially causes blindness and is due to diabetes.

Electrocardiogram – Record of the electrical activity of the heart, using high-frequency sound waves. With each beat, an electrical impulse (or "wave") travels through the heart. This wave causes the muscle to squeeze and pump blood from the heart. This test allows clinicians to diagnose abnormal heart conditions.

Fiber optic endoscopy – Procedure that allows a physician to insert a scope that enables examination of a patient's anatomy or physiology, such as the swallowing mechanism.

Glucose – Sugar.

Glycoprotein inhibitor – Class of drugs that inhibit proteins that cause clot formation; often used in the management of cardiovascular patients.

Hemoglobin A1c – Measure of blood glucose levels captured in a lab evaluation that provides an average of blood glucose levels over 2-3 months.

Hemorrhagic stroke – Accounting for 20-30% of all strokes, this occurs as a result of bleeding inside the brain, has a much higher death rate than ischemic strokes and is classified as sub-arachnoid hemorrhagic stroke (blood vessel on the brain's surface ruptures and bleeds into the space between the brain and the skull, but not into the brain itself) or cerebral hemorrhagic stroke (defective artery in the brain bursts, flooding the surrounding tissue with blood).

HER2 receptors – Human epidermal growth factor receptors. An overexpression (large increase) of these receptors on the cell's surface is a key factor in malignant transformation and is predictive of a poor prognosis in breast cancer.

Implantable Cardiac Defibrillator (ICD) – Device that delivers pacing or electric counter-shock to the heart when an abnormal rhythm is detected.

Ischemic stroke – Accounting for 70-80% of all strokes, this occurs when a blood clot forms and blocks blood flow in an artery bringing blood to part of the brain.

Lumpectomy – Type of breast conserving surgery used with breast cancer in which only the affected "lump" is removed (vs. the entire breast).

Lymphedema – Swelling of the arm.

Magnetic Resonance Imaging (MRI) – Method of gathering images of organs by using nuclear magnetic resonance of protons to produce proton density images.

Mastectomy – Complete removal of the breast.

Microalbuminuria – Elevated levels of urinary albumin (protein manufactured by the liver that assists in keeping liquid in the blood stream instead of leaking into the tissue). Also refers to a test used to diagnose a kidney disorder and conducted after a diagnosis of diabetes or hypertension.

Microcoil surgery – Minimally invasive surgical procedure used to treat aneurysms, which can often lead to stroke if not treated.

Microvascular complications – Collective term that refers to diabetic retinopathy, neuropathy, and nephropathy.

Percutaneous Coronary Intervention (PCI) – Collective term used to describe minimally invasive cardiovascular procedures, such as angioplasty and stenting.

Percutaneous Transluminal Coronary Angioplasty (PTCA) – See angioplasty.

Photocoagulation therapy – Laser surgery used to seal leaks in retinal blood vessels, preventing further vision loss.

Positron Emission Tomography (PET) – Scan that uses a small dosage of a chemical called radionuclide combined with a sugar. A PET scanner detects the positron emissions given off by the radionuclide. The imaging technique is used for diagnosis of a variety of conditions including breast cancer and stroke.

Proteinuria – Elevated levels of protein in the urine, which may be a sign of kidney damage.

Quality-Adjusted Life-Year (QALY) – The expected number of additional years of life with improvements in the quality of life because of a health intervention.

Recombinant DNA (rDNA) – Taking DNA from one organism and introducing it into the DNA of bacteria where it then reproduces, making copies.

Recombinant Tissue-type Plasminogen Activator (rt-PA) – Type of thrombolytic drug used to dissolve clots but with a mode of action different from antiplatelets and streptokinase.

Restenosis – Re-narrowing of a blood vessel or heart valve that had been previously opened with angioplasty or drug therapy.

Revascularization – Process to restore blood flow to a body part through procedure-based interventions (angioplasty, stents, coronary artery bypass graft), or by dissolving blood clots with drug therapy.

SEER – Surveillance, epidemiology and end results program that is used to track cancer prevalence and incidence in the U.S.

Statin – Class of drugs that lower cholesterol levels by blocking enzymes essential to cholesterol production.

Stenosis – Abnormal narrowing or constriction of a blood vessel or valve in the heart (often due to an obstruction).

Stent – Tiny wire mesh device used to keep blood vessels open; classified as either bare-metal or drug-eluting.

Stereotactic core needle biopsy – Procedure to obtain tissue sample by taking two separate X-rays of the breast to locate the lump, and then, with only local anesthetic, using a needle to obtain a tissue sample.

Streptokinase – Type of thrombolytic drug used to dissolve clots but with a mode of action different from antiplatelets and recombinant tissue-type plasminogen activator.

Subarachnoid hemorrhage – Bleeding into the brain.

Sulfonylurea – One of the earliest classes of oral drug therapies used to treat diabetes.

Thiazolidinedione – Class of oral drugs used to treat diabetes by increasing muscle and fat insulin sensitivity.

Thrombolysis – Process of dissolving blood clots through drug therapy.

Thrombolytic – Drug used to dissolve or break up clots that block blood flow; also known as "clot-busting" drug.

Thrombosis – Formation of blood clots that block blood flow in coronary arteries and often cause heart attacks when left untreated.

Ticlopidine – Type of antiplatelet drug approved for use in the 1980s that minimizes risk of recurrent stroke.

Transverse Rectus Abdominis Myocutaneous (TRAM) flap – Most frequently used autologous tissue used for breast reconstruction.

Transesophageal echocardiography – Test that enables a clinician to view the internal structures of the heart and the heart's major vessels by inserting a probe down the patient's throat.

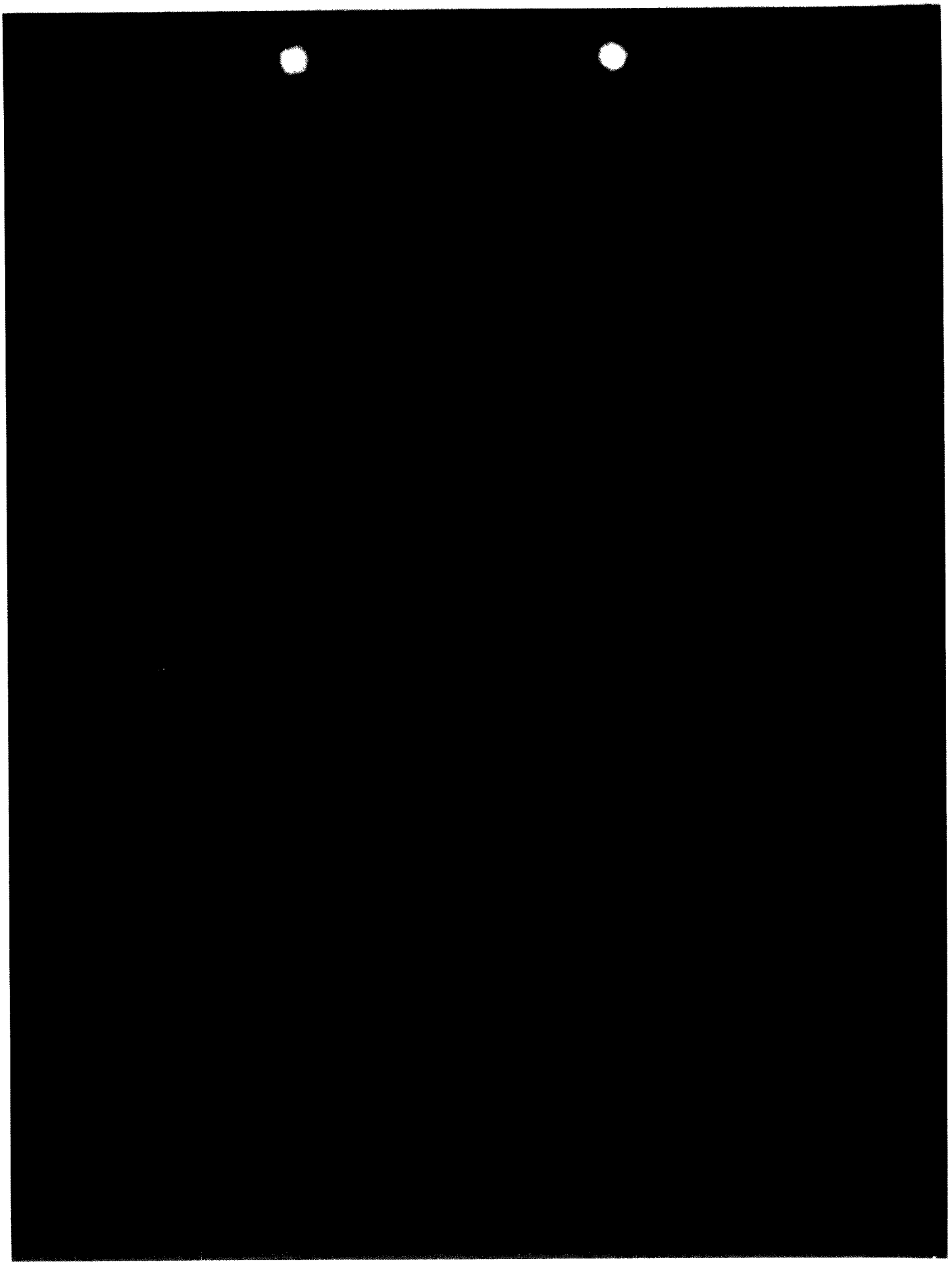
Transient ischemic attack – Also known as a "mini-stroke," this occurs when brain cells temporarily stop working because of insufficient oxygen, causing stroke-like symptoms that resolve completely within 24 hours of onset.

Transthoracic echocardiography – Also known as an ECHO, this diagnostic test enables a clinician to check for problems in and around a patient's heart using a probe on the surface of the chest.

Ultrasound – High-frequency sound vibration that can be translated into an image and is often used to make medical diagnoses.

Ventricular arrhythmias – Irregular heartbeat (classified as ventricular fibrillation or tachycardia).

Vitrectomy – Surgical removal of the vitreous (normally clear, gel-like substance that fills the center of the eye, making up approximately 2/3 of the eye's volume, giving it form and shape before birth).



AdvaMed
Advanced Medical Technology Association
www.advamed.org

American College of Cardiology
www.acc.org

American Hospital Association
www.aha.org

Federation of American Hospitals
www.americashospitals.com

Healthcare Leadership Council
www.hlc.org

NPC
National Pharmaceutical Council
www.npcnow.com

PhRMA
Pharmaceutical Research and Manufacturers of America
www.phrma.org

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For additional information or to review the full report, please visit the MEDTAP website at www.MEDTAP.com.

Docket Management Comment Form

Docket: 2004S-0233 - Solicitation of Comments on Stimulating Innovation in Medical Technologies

Temporary Comment Number: 4827

Submitter: Mr. Blair Childs **Date:** 08/23/04

Organization: Value Group

Category: Health Care Association

Issue Areas/Comments

Questions
1. What strategies and approaches could HHS implement to accelerate the development and application of new medical technologies?
See Attachment

Questions
2. How can HHS help its agencies (e.g., NIH (and its grantees), FDA, CDC, and CMS) to work together more effectively to eliminate obstacles to development of medical technologies?
See Attachment

Questions
3. How can the HHS scientific and regulatory agencies work more effectively with CMS to eliminate obstacles to development?
See Attachment

Questions
4. What forums should HHS use to survey constituents about obstacles in innovation (e.g., public meetings, contract research, focus groups)?
See Attachment

Questions
5. How can the portability of informaion between HHS agencies be optimized?
See Attachment

Questions
6. Which HHS policies and programs effectively spur innovation?
See Attachment

General
See Attachment

Attachments
No Attachments

Print | Comment on Another Docket | Exit

Print - Print the comment

Exit - Leave the application