Decision Making in Cardiac Therapeutics: Ethics, History, and Policy

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DISCLOSURE

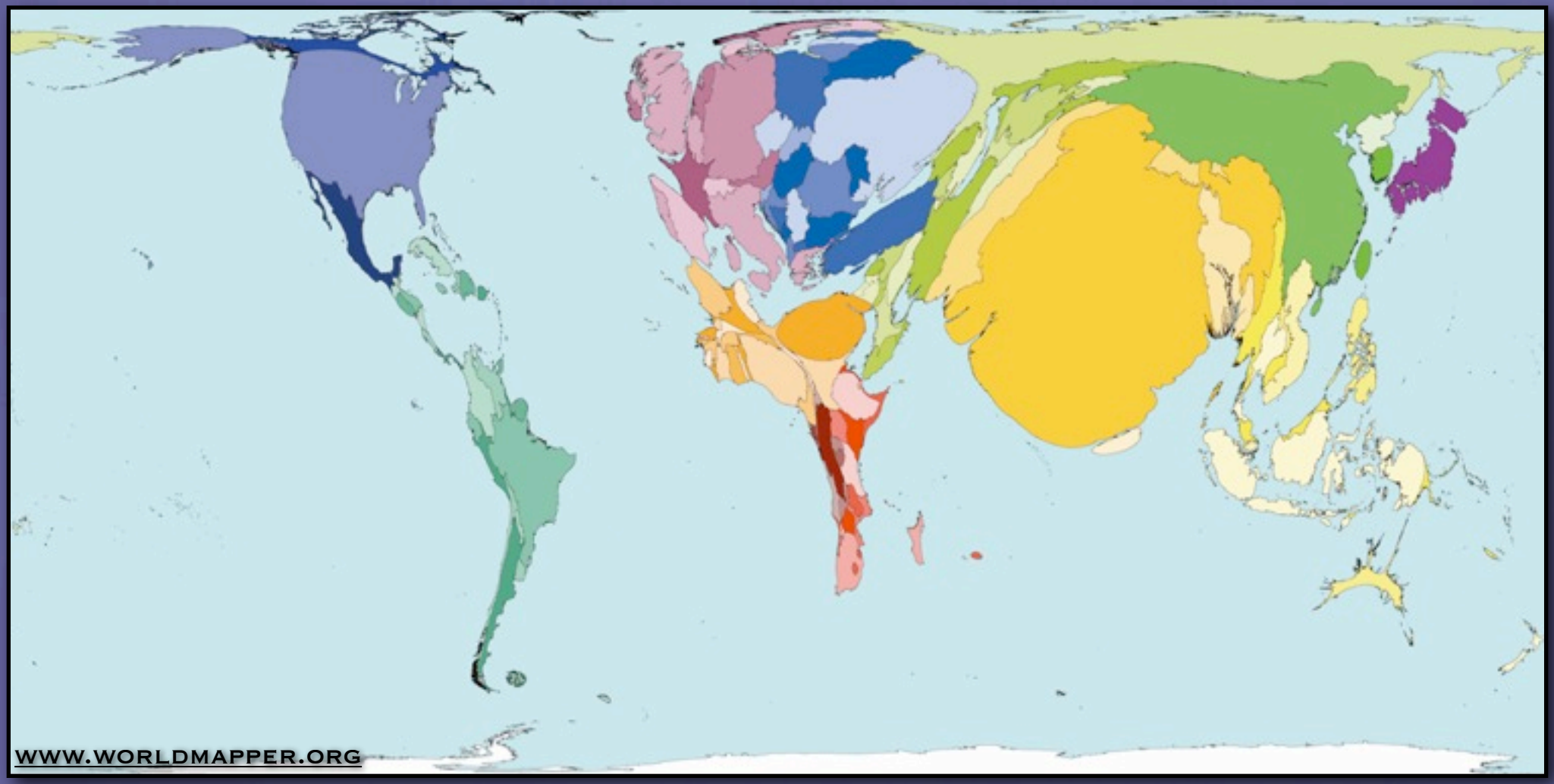
I have no financial relationship with a commercial entity producing health-care related products and/or services.

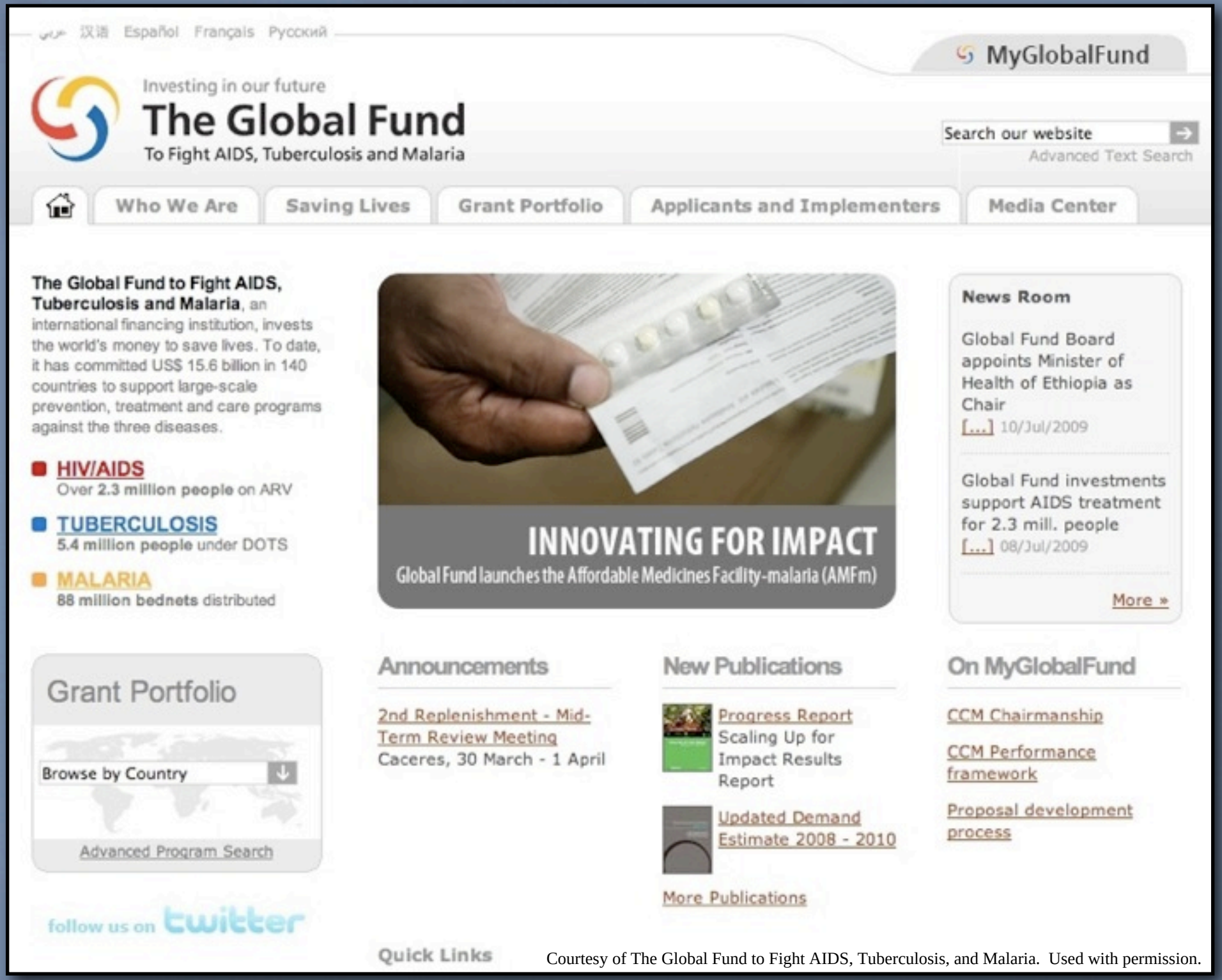
What Is Social Medicine?

- Social Determinants of Disease
- Social Meanings of Disease
- Social Responses to Disease

- Practice: Health Care Delivery
- Medical Epistemology: how do we know what we know

Heart Attack Deaths



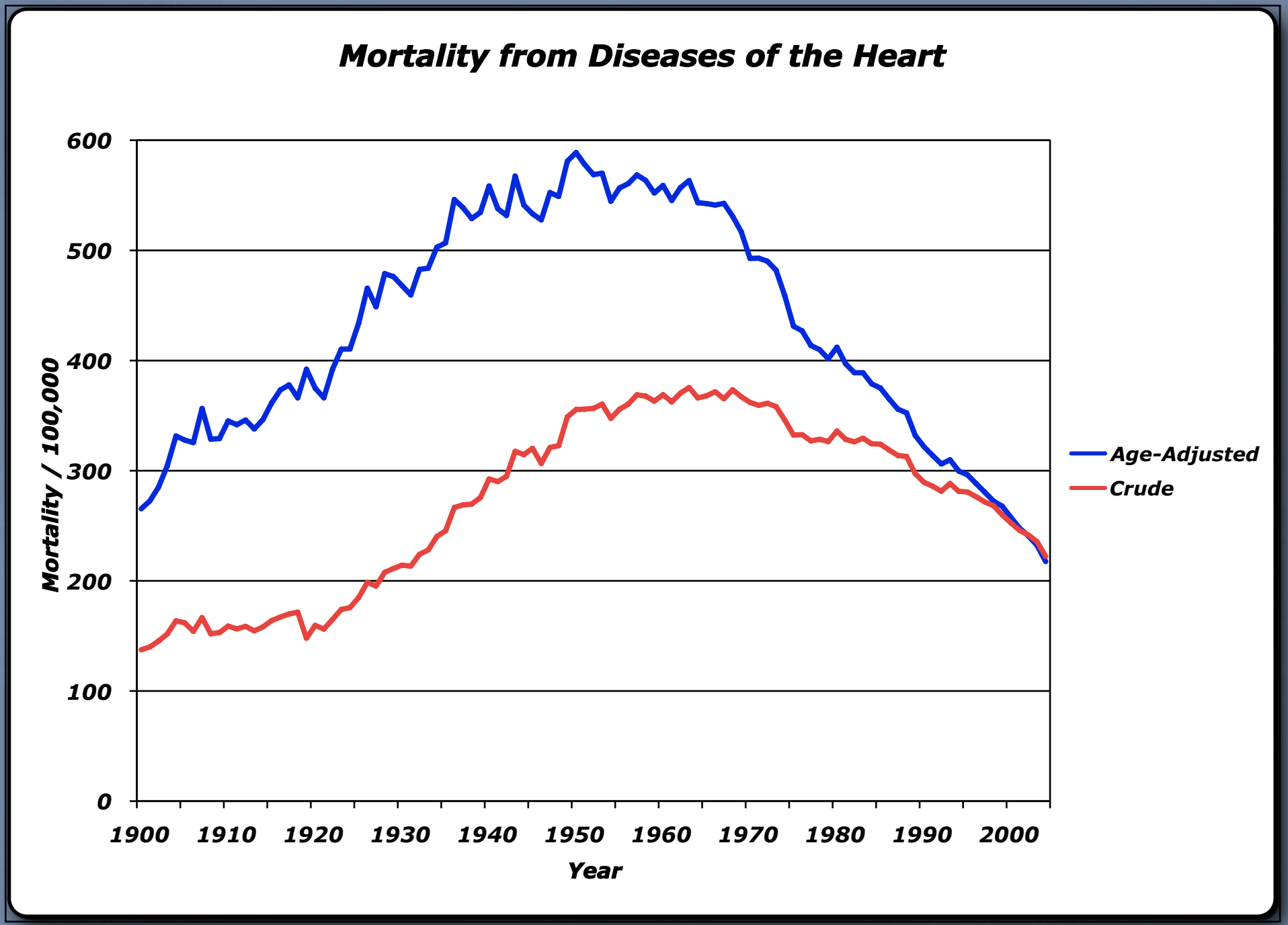


Courtesy of The Global Fund to Fight AIDS, Tuberculosis, and Malaria. Used with permission.

The best Rx for AMI is PCI? How do we know?

Painting by Frank Netter, M.D. of man suffering from angina pectoris, chest pain due to coronary artery disease, removed due to copyright restrictions.

Photo of coronary angioplasty removed due to copyright restrictions.


Mortality from Diseases of the Heart
600
500
400
300
200
100
0
Mortality / 100,000
1900
1910
1920
1930
1940
1950
1960
1970
1980
1990
2000
Year
Age-Adjusted
Crude

Risk Factors

Other Risks?

Fig. 1. Occupational class differences in life expectancy, England and Wales, 1997–1999

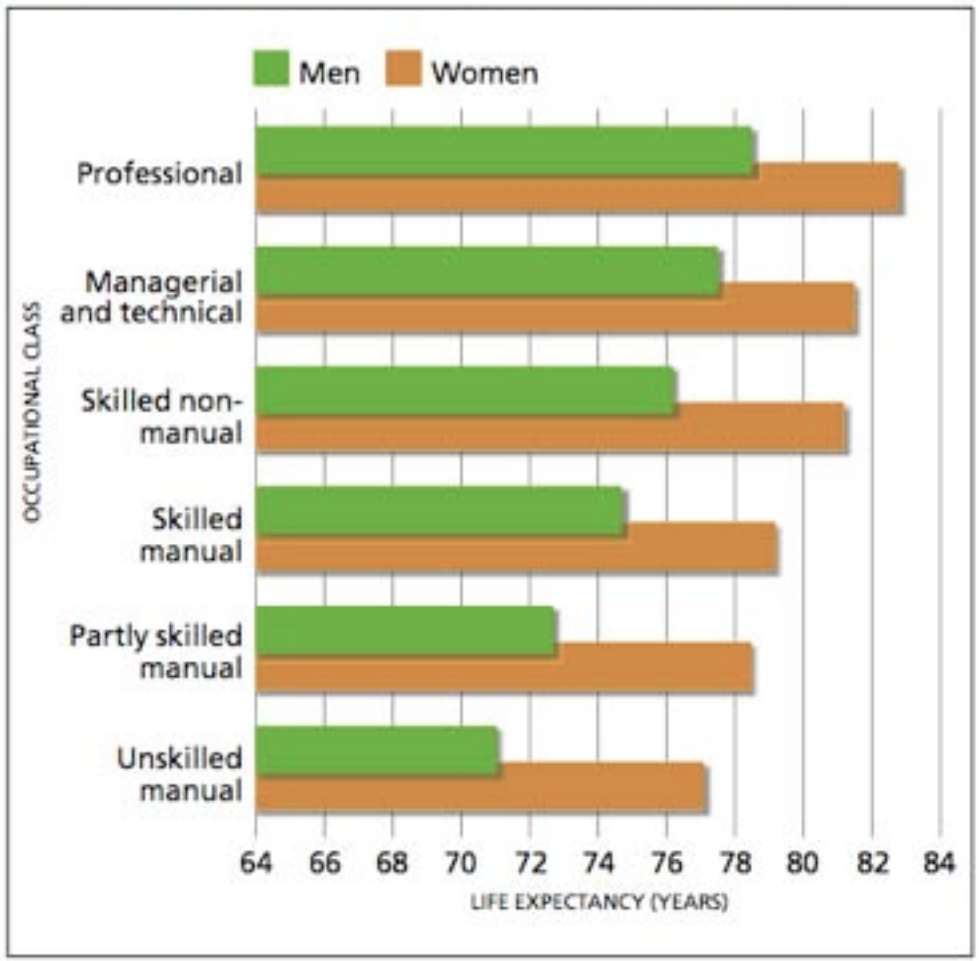
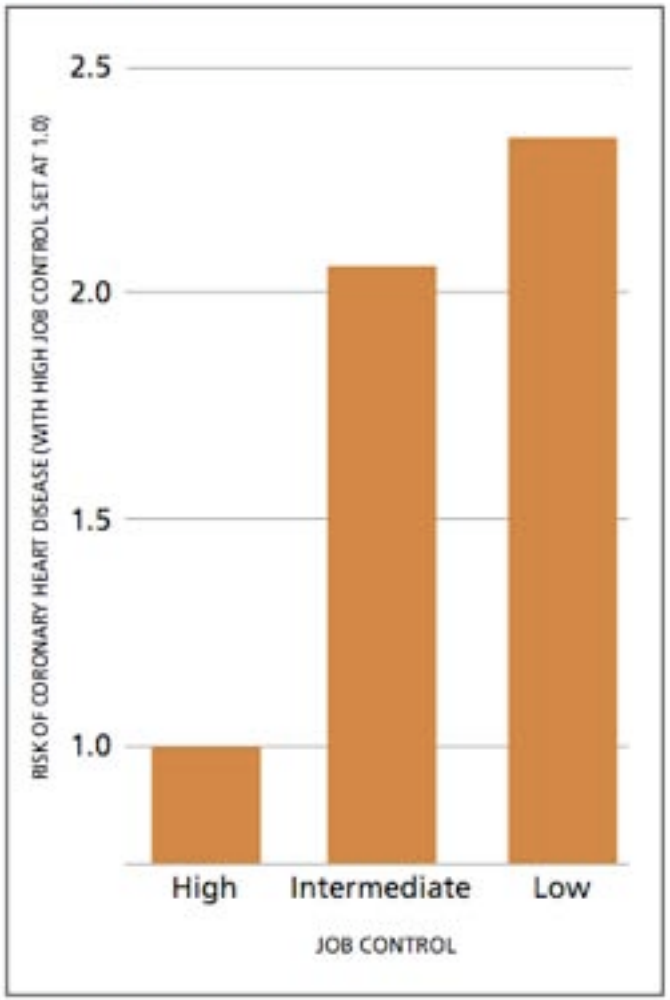


Fig. 4. Self-reported level of job control and incidence of coronary heart disease in men and women



Adjusted for age, sex, length of follow-up, effort/reward imbalance, employment grade, coronary risk factors and negative psychological disposition

CAD as a Disease of Elites

- Warren Harding
- Calvin Coolidge
- Dwight D. Eisenhower
- Lyndon Johnson

Photo of President Dwight D. Eisenhower in wheelchair removed due to copyright restrictions.

Race and Differential Susceptibility?

Public domain photo from U.S. National Archives and Records Administration.

Do not feel stress, or cannot handle it

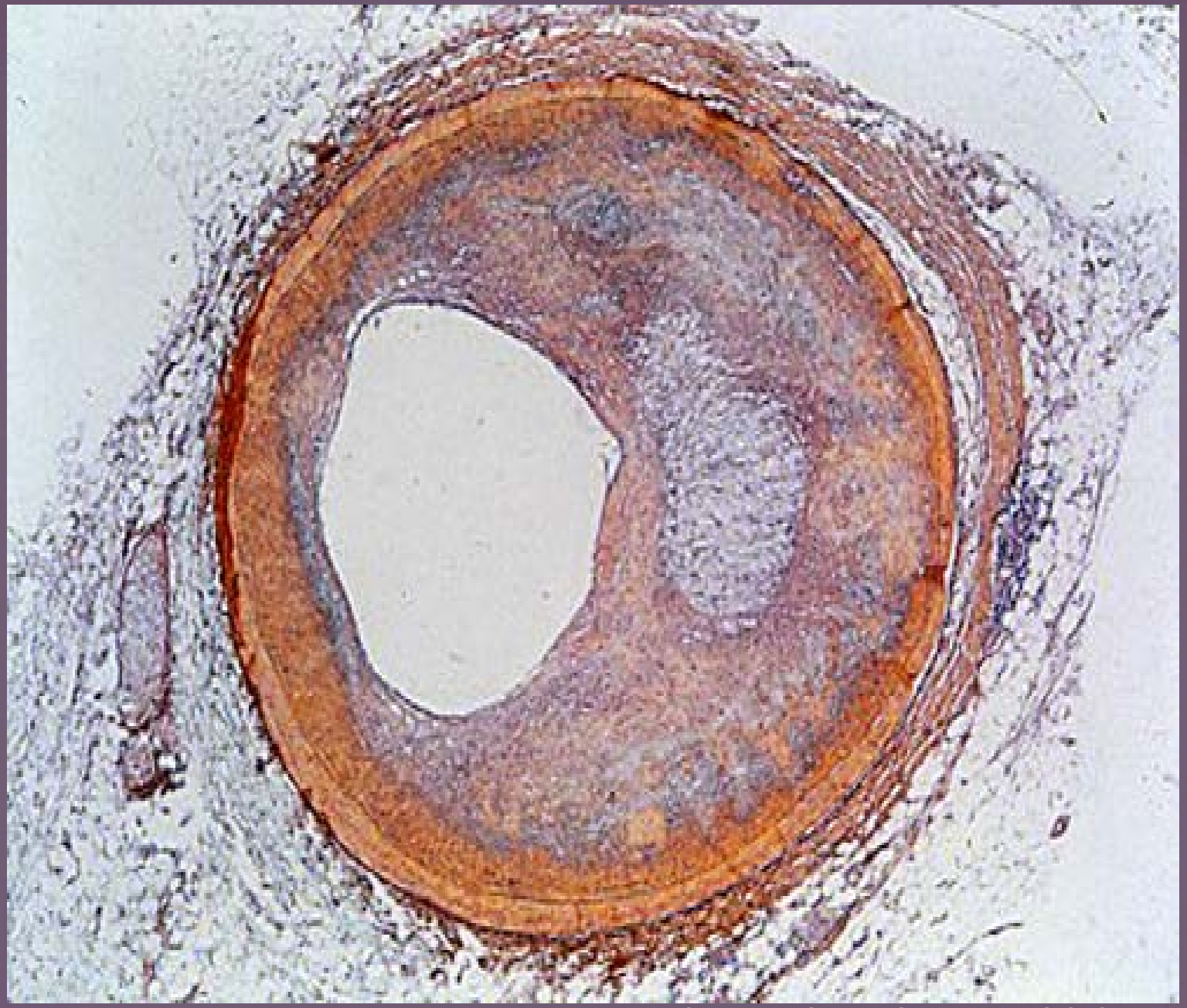
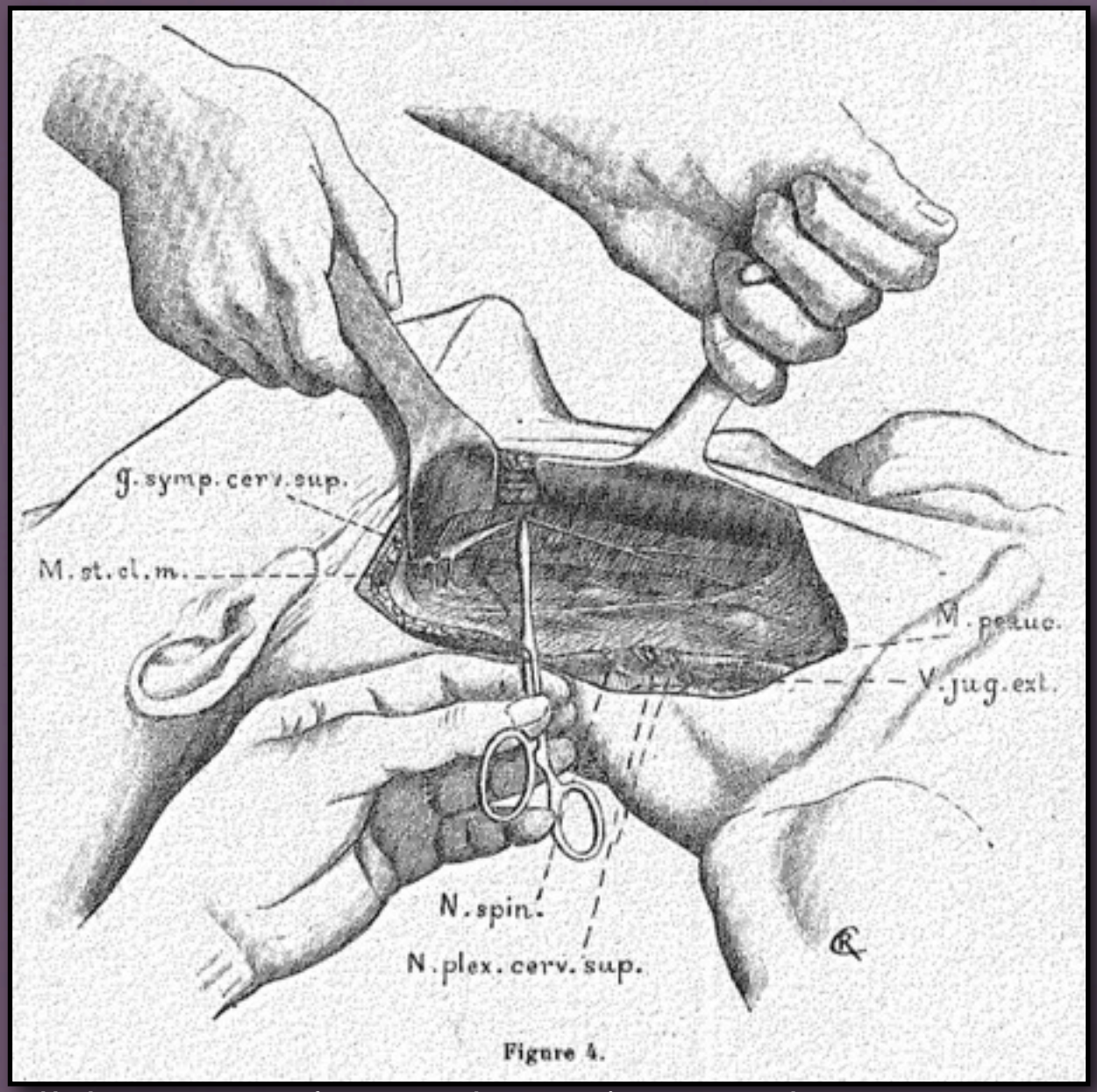


Photo courtesy the National Heart, Lung, and Blood Institute.

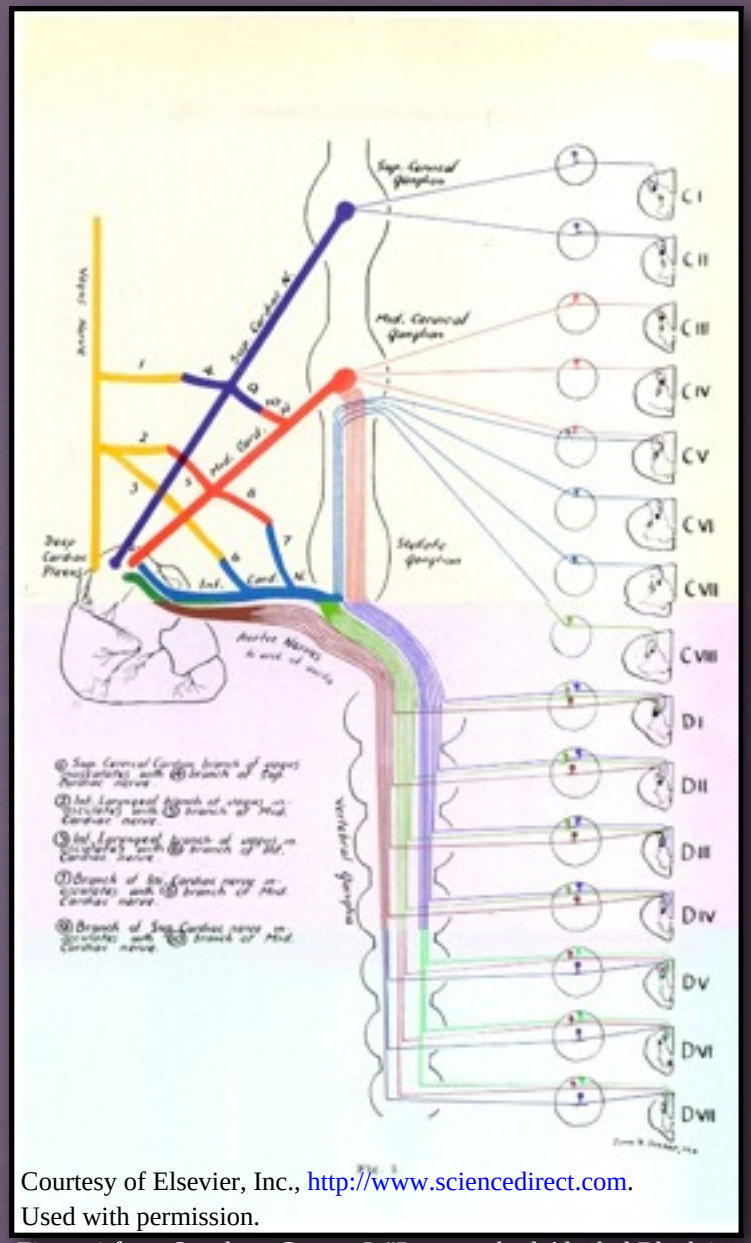
How to treat coronary artery disease?

Excerpts from *New England Journal of Medicine* removed due to copyright restrictions. For complete article, see Sproull, John. "A General Practitioner's Views on the Treatment of Angina Pectoris." *New England Journal of Medicine* 215, no. 10 (1936).

Reduce Demand:
Disrupt sympathetic nervous system



Public domain image. Figure 4 from Jonnesco, Thomas. "La Résection Du Sympathique Cervico-Thoracique: Technique Opératoire." *La Presse Médicale*, no. 33 (1922).



Courtesy of Elsevier, Inc., http://www.sciencedirect.com.
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Figure 1 from Swetlow, George I. "Paravertebral Alcohol Block in Cardiac Pain." *The American Heart Journal* 1, no. 4 (1926).

Reduce Demand:
Thyroid Ablation (surgery, radiation)

Photos of patient seven years before operation, and three years and six months after operation from *Annals of Surgery* removed due to copyright restrictions. For complete article, see Cutler, Elliott C., and Stanley O. Hoerr. "Total thyroidectomy for heart disease: A five-year follow-up study." *Annals of Surgery* 113, no. 2 (1941).

Informal Claims of Efficacy

Excerpt from *The New York Times* removed due to copyright restrictions.
For complete article, see "'Simple' Surgery Called Heart Aid: Physician Hopeful Method Will Help End Effects of Coronary Thrombosis." *The New York Times*, February 6, 1957.

Excerpt from *Journal of Thoracic Surgery* removed due to copyright restrictions.
For complete article, see Glover, Robert P. et al. "Ligation of the Internal Mammary Arteries as a Means of Increasing Blood Supply to the Myocardium." *Journal of Thoracic Surgery* 34, no. 5 (1957).

77 PATIENTS: 36% CURED, 32% IMPROVED

Excerpt from *American Journal of Cardiology* removed due to copyright restrictions.
For complete article, see Dimond, Grey, C. Frederick Kittle, and James E. Crockett.
"Comparison of Internal Mammary Artery Ligation and Sham Operation for Angina Pectoris."
American Journal of Cardiology 5 (1960).

Excerpt and Table 1 from Journal of the *American Medical Association* removed due to copyright restrictions. For complete article, see Beecher, Henry K. "Surgery as Placebo: A Quantitative Study of Bias." *Journal of the American Medical Association* 176, no. 13 (1961).

Increase Supply: Create or provide new conduits for blood

Three figures of surgery to treat coronary artery disease removed due to copyright restrictions. See Beck, Claude S., and David S. Leighninger. "Scientific Basis for the Surgical Treatment of Coronary Artery Disease." *Journal of the American Medical Association* 159, no. 13 (1955).

Figure 7 of interal mammary artery implantation from *Diseases of the Chest* removed due to copyright restrictions. For complete article, see Vineberg, Arthur. "The Bloodless Greater Omentum for Myocardial Revascularization." *Diseases of the Chest* 54, no. 4 (1968).

Re-engineering the body...

Internal Mammary Artery Implant

Figure 7 from *Annals of Surgery* removed due to copyright restrictions. For complete article, see Effler, Donald B. et al. "Increased Myocardial Perfusion by Internal Mammary Artery Implant: Vineberg's Operation." *Annals of Surgery* 158, no. 4 (1963).

Selective Coronary Angiography

Figures 1, 4, and 5 from *Circulation* removed due to copyright restrictions. For complete article, see Lemmon, William M., Stauffer Lehman, and Randal A. Boyer. "Suprasternal Transaortic Coronary Arteriography." *Circulation* 19 (1959).

Photo of Mason Sones, c. 1960 at the Cleveland Clinic removed due to copyright restrictions.

Mason Sones
Cine-angiography

1958

January 12, 1962: Visual Proof?

Figure 9 from *Annals of Surgery* removed due to copyright restrictions. For complete article, see Effler, Donald B. et al. "Increased Myocardial Perfusion by Internal Mammary Artery Implant: Vineberg's Operation." *Annals of Surgery* 158, no. 4 (1963).

Endarterectomies and Patch Grafts

"Instant revascularization"

Figure from Scientific American removed due to copyright restrictions.
See page 41 of Effler, Donald B. "Surgery for Coronary Disease." *Scientific American*, October 1968.

Bypass Surgery

Photo of completed coronary artery bypass surgery removed due to copyright restrictions.

Cover page of *Cleveland Magazine*, November 1973 removed due to copyright restrictions.

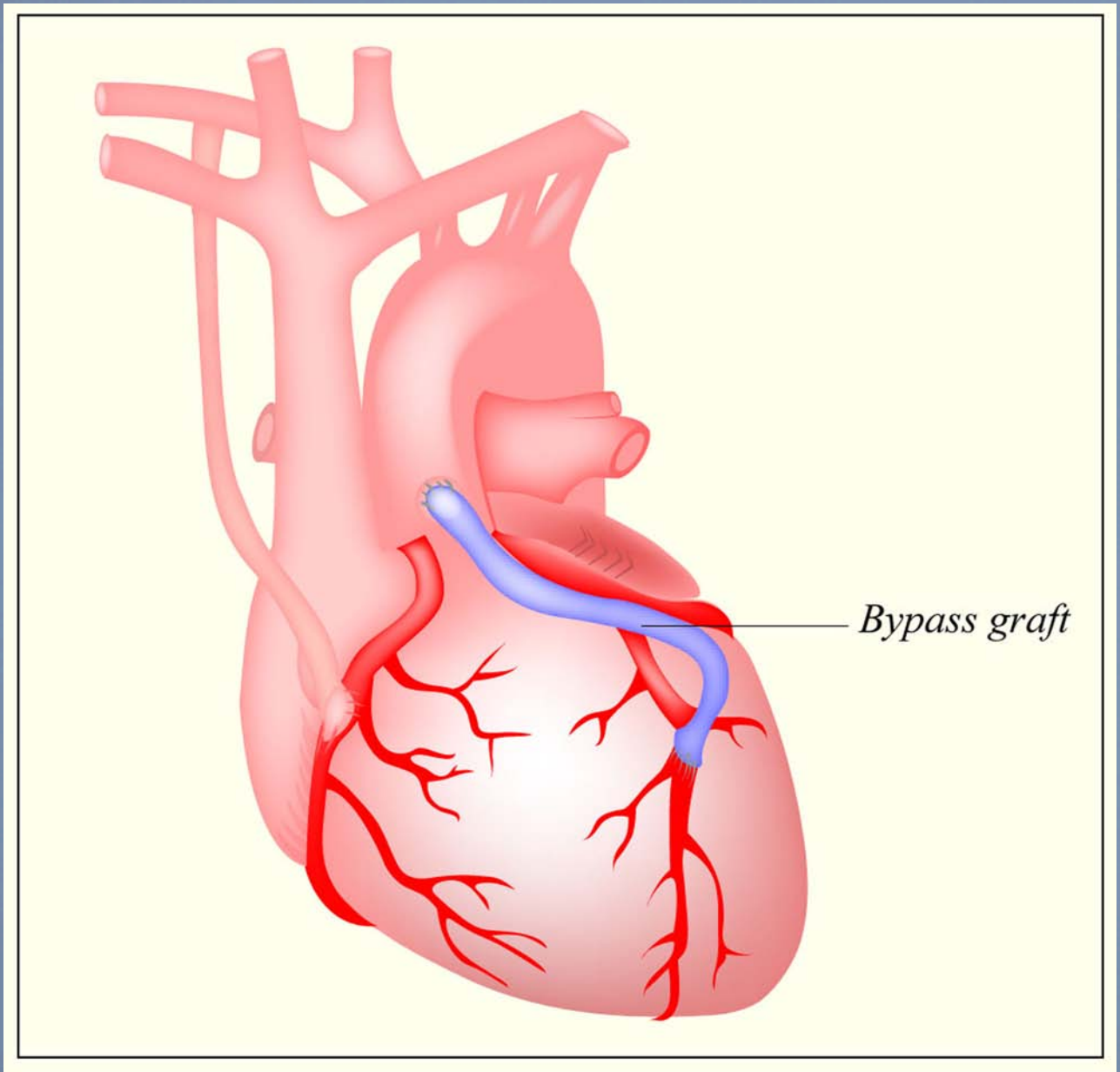


Image by MIT OpenCourseWare.
Adapted from Cleveland Clinic.

Does Size Matter?

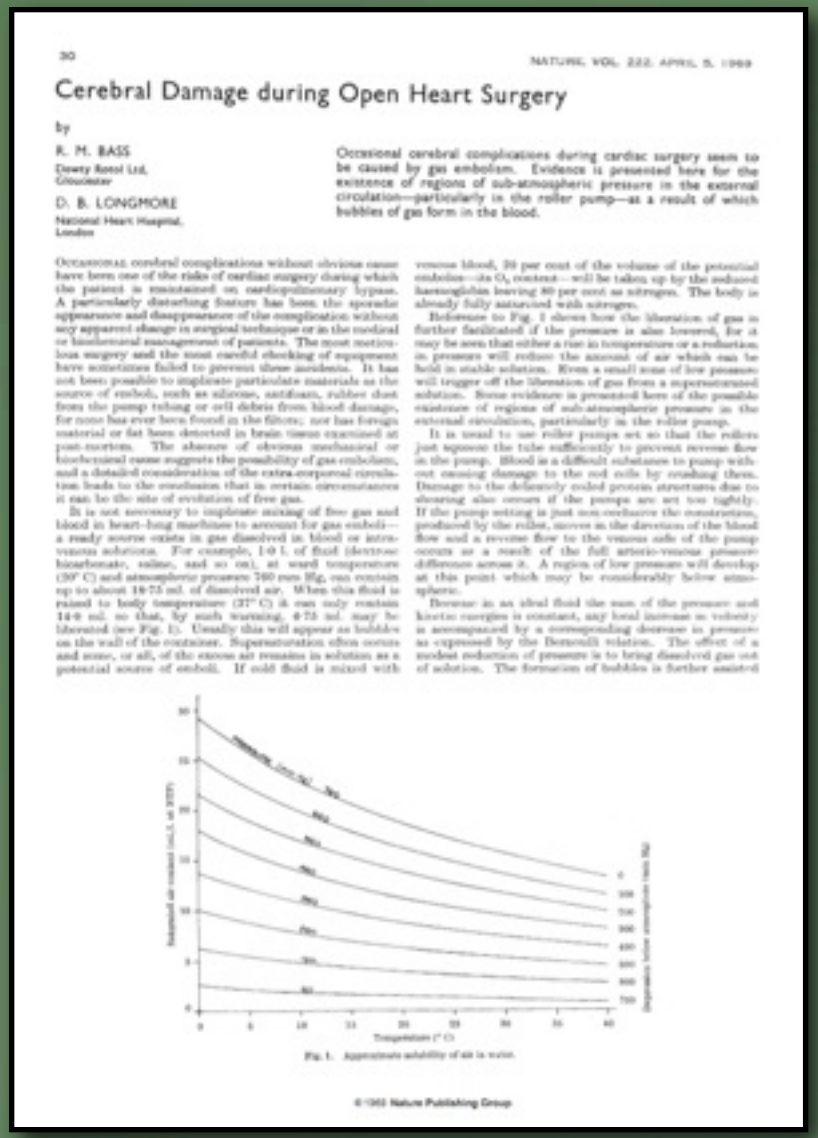
Image of heart showing aortocoronary bypass removed due to copyright restrictions.
See Sandiford, Frank M., Denton A. Cooley, and Don C. Wukasch. "The Aortocoronary Bypass Operation: Myth and Reality. An Overview Based on 10,000 Operations at the Texas Heart Institute." *International Surgery* 63, no. 4 (1978).


Photo of patient undergoing procedure removed due to copyright restrictions.

Excerpt from *New England Journal of Medicine* removed due to copyright restrictions.
For complete article, see Murphy, Marvin L. et al. "Treatment of Chronic Stable Angina.
A Preliminary Report of Survival Data of the Randomized Veterans Administration Cooperative Study."
New England Journal of Medicine 297, no. 12 (1977).

Are RCT's Right for Surgery?

Complications of Cardiac Surgery



30 NATURE, VOL. 222, APRIL 5, 1969

Cerebral Damage during Open Heart Surgery

by

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Dewy Road Ltd,
Gloucester

D. B. LONGMORE
National Heart Hospital,
London

Occasional cerebral complications during cardiac surgery seem to be caused by gas embolism. Evidence is presented here for the existence of regions of sub-atmospheric pressure in the external circulation—particularly in the roller pump—as a result of which bubbles of gas form in the blood.

OCCASIONAL cerebral complications without obvious cause have been one of the risks of cardiac surgery during which the patient is maintained on cardiopulmonary bypass. A particularly disturbing feature has been the sporadic appearance and disappearance of the complication without any apparent change in surgical technique or in the medical or biochemical management of patients. The most meticulous surgery and the most careful checking of equipment have sometimes failed to prevent these accidents. It has not been possible to implicate particulate materials as the source of emboli, such as silicone, antifoam, rubber dust from the pump tubing or oil debris from blood damage, for none has ever been found in the filters; nor has foreign material or fat been detected in brain tissue examined at post-mortem. The absence of obvious mechanical or biochemical cause suggests the possibility of gas embolism, and a detailed consideration of the extra-corporeal circulation leads to the conclusion that in certain circumstances it can be the site of evolution of free gas.

It is not necessary to implicate mixing of free gas and blood in heart–lung machines to account for gas emboli—a ready source exists in gas dissolved in blood or intravenous solutions. For example, 1·0 l. of fluid (dextrose bicarbonate, saline, and so on), at ward temperature (20° C) and atmospheric pressure 760 mm Hg, can contain up to about 18·75 ml. of dissolved air. When this fluid is raised to body temperature (37° C) it can only contain 14·0 ml. so that, by such warming, 4·75 ml. may be liberated (see Fig. 1). Usually this will appear as bubbles on the wall of the container. Supersaturation often occurs and some, or all, of the excess air remains in solution as a potential source of emboli. If cold fluid is mixed with venous blood, 10 per cent of the volume of the potential embolus—its O_2 content—will be taken up by the reduced haemoglobin leaving 80 per cent as nitrogen. The body is already fully saturated with nitrogen.

Reference to Fig. 1 shows how the liberation of gas is further facilitated if the pressure is also lowered, for it may be seen that either a rise in temperature or a reduction in pressure will reduce the amount of air which can be held in stable solution. Even a small zone of low pressure will trigger off the liberation of gas from a supersaturated solution. Some evidence is presented here of the possible existence of regions of sub-atmospheric pressure in the external circulation, particularly in the roller pump.

It is usual to use roller pumps set so that the rollers just squeeze the tube sufficiently to prevent reverse flow in the pump. Blood is a difficult substance to pump without causing damage to the red cells by crushing them. Damage to the delicately coiled protein structure due to shearing also occurs if the pumps are set too tightly. If the pump setting is just non-occlusive the constrictions, produced by the rollers, moves in the direction of the blood flow and a reverse flow to the venous side of the pump occurs as a result of the full arterio-venous pressure difference across it. A region of low pressure will develop at this point which may be considerably below atmospheric.

Because in an ideal fluid the sum of the pressure and kinetic energies is constant, any local increase in velocity is accompanied by a corresponding decrease in pressure as expressed by the Bernoulli relation. The effect of a modest reduction of pressure is to bring dissolved gas out of solution. The formation of bubbles is further assisted

Fig. 1. Approximate solubility of air in water.

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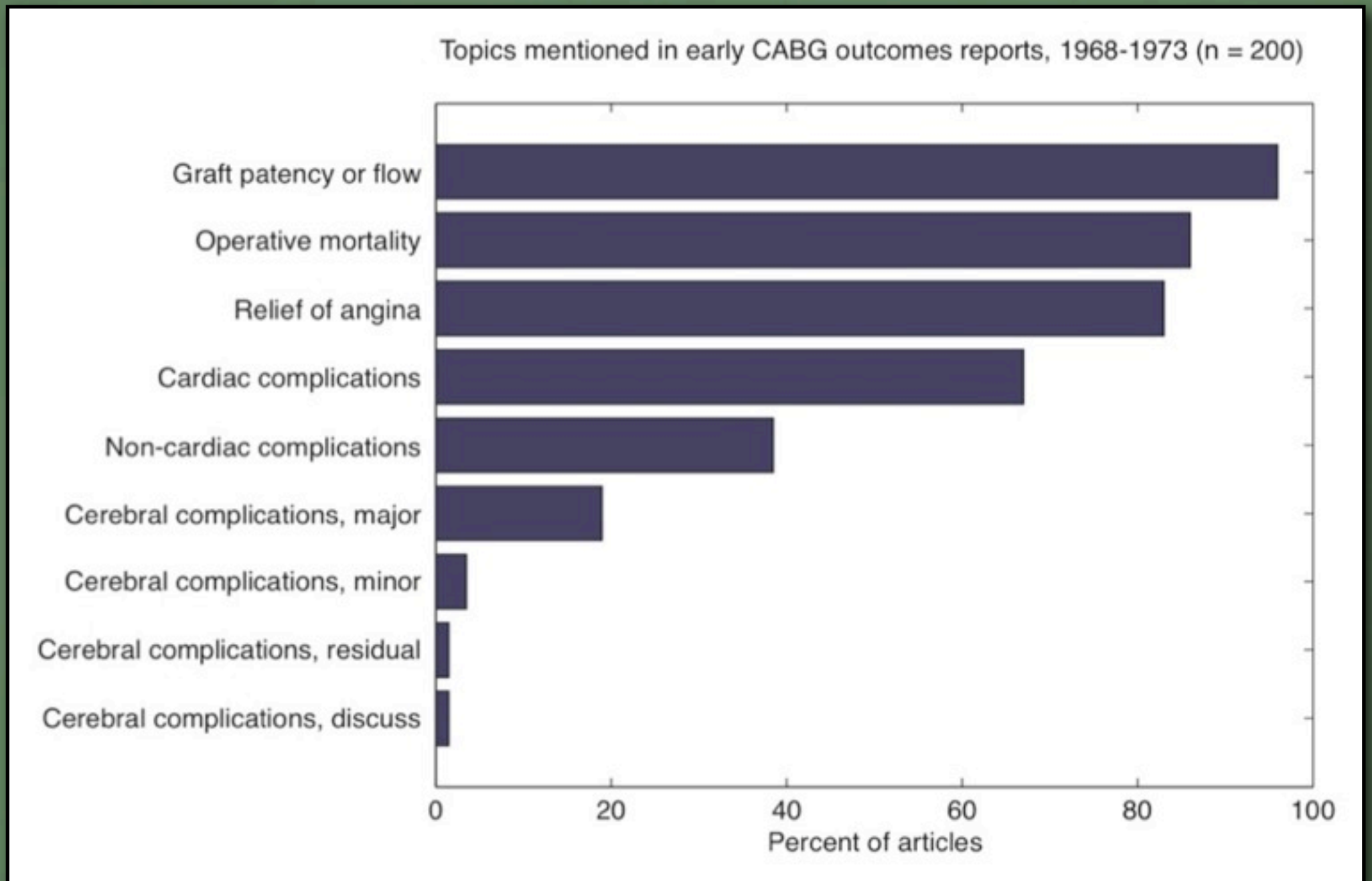
Excerpt from *New England Journal of Medicine* removed due to copyright restrictions. For complete article, see Gilman, Sid. "Cerebral Disorders After Open-Heart Operations." *New England Journal of Medicine 272, no. 10 (1965).*

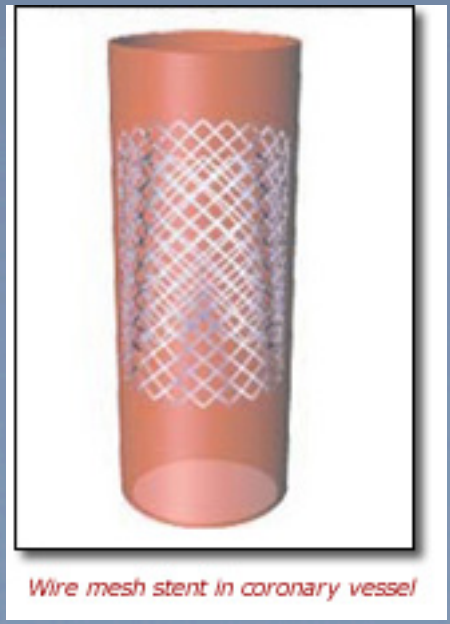
Excerpt and figure from the *Journal of the American Medical Association* removed due to copyright restrictions. For complete article, see Tufo, Henry M. "Central Nervous System Dysfunction Following Open-Heart Surgery." *Journal of the American Medical Association* 212, no. 8 (1970).


Topics mentioned in early CABG outcomes reports, 1968-1973 (n = 200)
Graft patency or flow
Operative mortality
Relief of angina
Cardiac complications
Non-cardiac complications
Cerebral complications, major
Cerebral complications, minor
Cerebral complications, residual
Cerebral complications, discuss
0
20
40
60
80
100
Percent of articles

Excerpt from *Vanity Fair* with photo of former President Bill Clinton removed due to copyright restrictions. For complete article, see Purdum, Todd S. "The Comeback Id." *Vanity Fair*, July 2008. http://www.vanityfair.com/politics/features/2008/07/clinton200807 (accessed September 23, 2010).

"Pump Head"?

Excerpt from October 1979 article on balloon dilation from Texas Heart Institute removed due to copyright restrictions.



Wire mesh stent in coronary vessel

Image courtesy www.genome.gov.

Angioplasty

Angiography photo of oculostenotic reflex removed due to copyright restrictions.

The "oculo-stenotic reflex"

a compulsion to treat?

Plaque Rupture

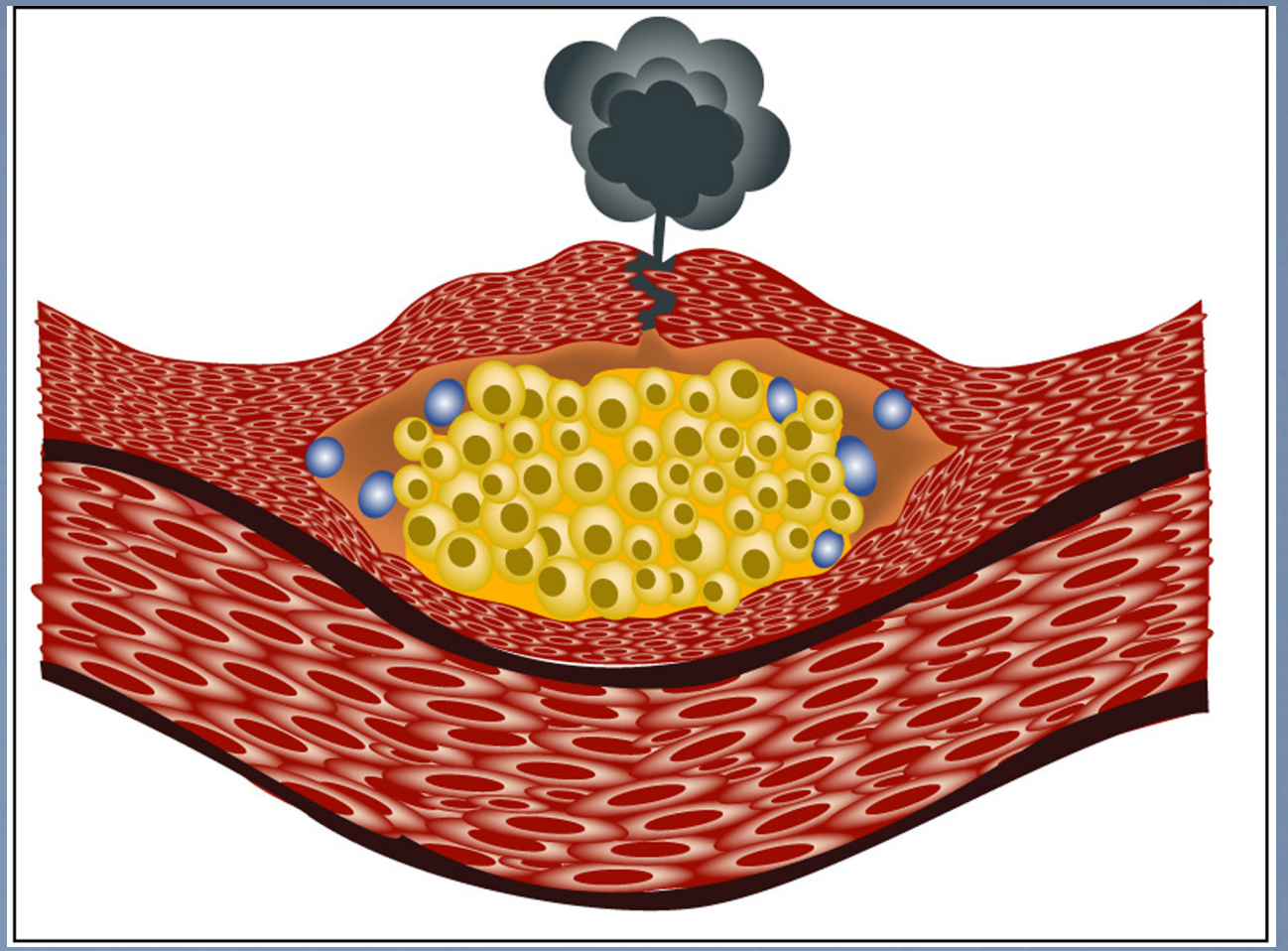


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Image of "About Us" page from www.volcanocorp.com removed due to copyright restrictions.
Volcano Corporation manufactures intravascular ultrasound (IVUS) products to measure
the status of heart disease and to confirm correct expansion of stents following placement.

Plavix brochure "How do Clots Form?" removed due to copyright restrictions.

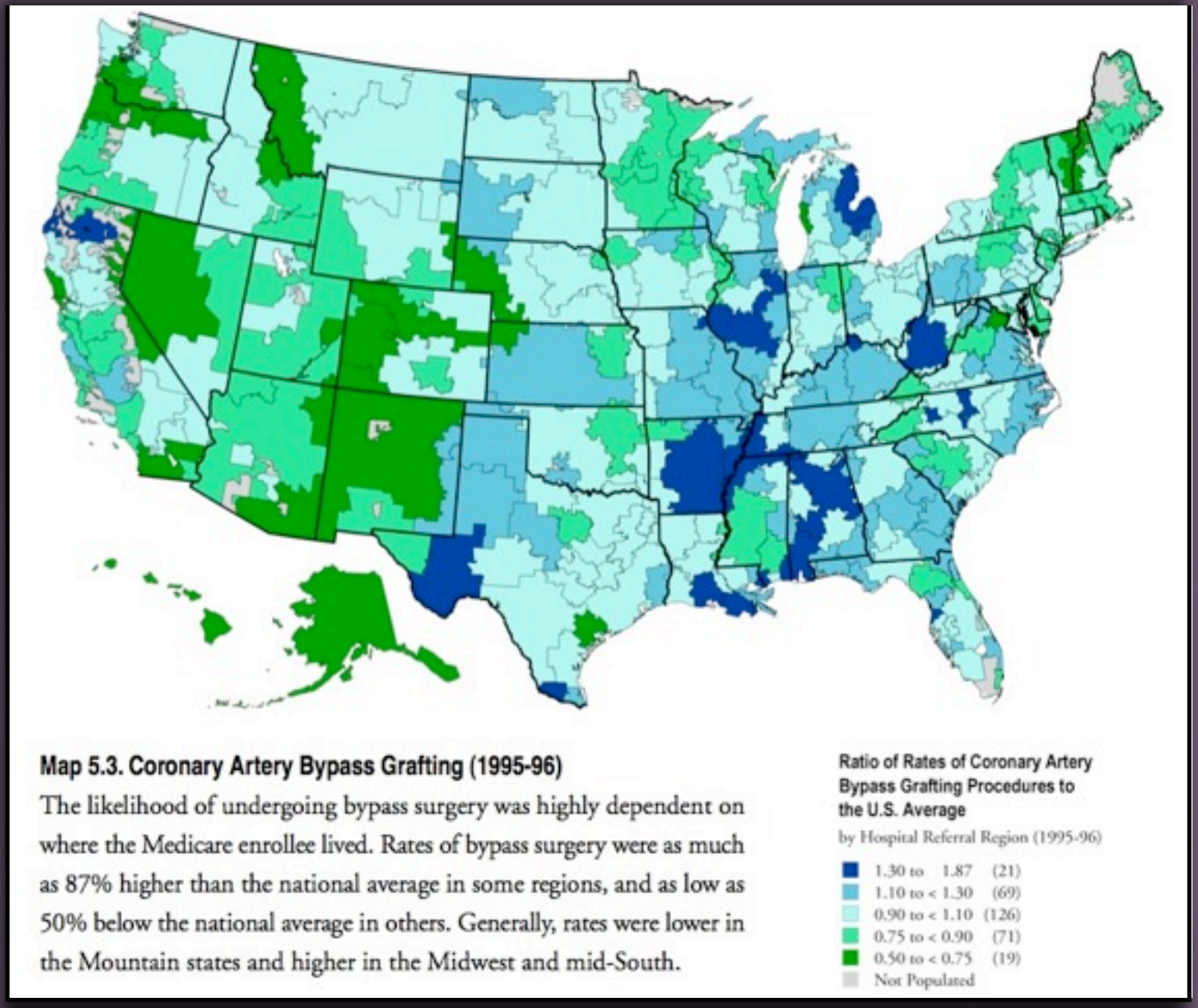
Advertisement for Lipitor removed due to copyright restrictions.

Disease Models and Treatments

Photo from *New York Times* of patient in hospital as he recovered from second heart attack and subsequent angioplasty removed due to copyright restrictions. See article Kolta, Gina. "Lessons of Heart Disease, Learned and Ignored." *The New York Times*, April 8, 2007. (accessed September 23, 2010).

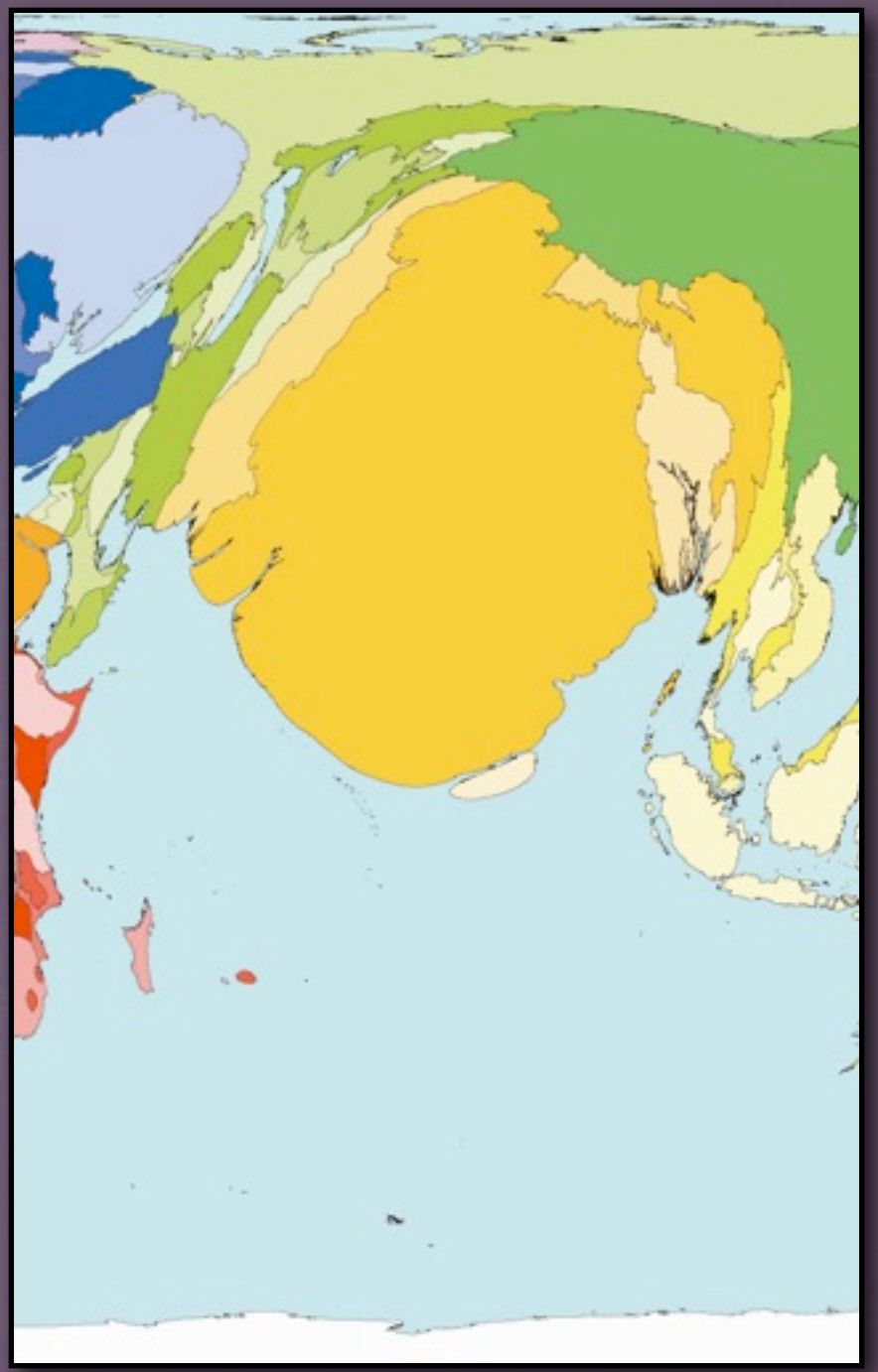
What should we do?

Unwarranted Variation?



Map 5.3 from Wennberg, John E. and the Dartmouth Atlas of Health Care Working Group. "The Quality of Medical Care in the United States: A Report on the Medicare Program. The Dartmouth Atlas of Health Care 1999." Copyright the Trustees of Dartmouth College. Used with permission. To access complete report, visit http://www.dartmouthatlas.org/.

- Why has there been so little attention?
- What is an appropriate response?



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Spring 2010