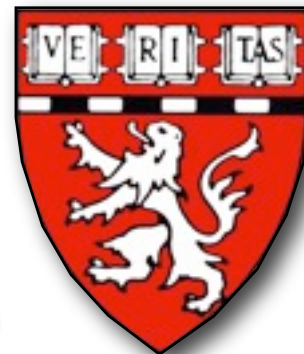


# DECISION MAKING IN CARDIAC THERAPEUTICS: ETHICS, HISTORY, AND POLICY

DAVID S. JONES, M.D., PH.D.

11 FEBRUARY 2010

PROGRAM IN SCIENCE, TECHNOLOGY, AND SOCIETY, MIT  
DEPARTMENT OF GLOBAL HEALTH AND SOCIAL MEDICINE, HMS



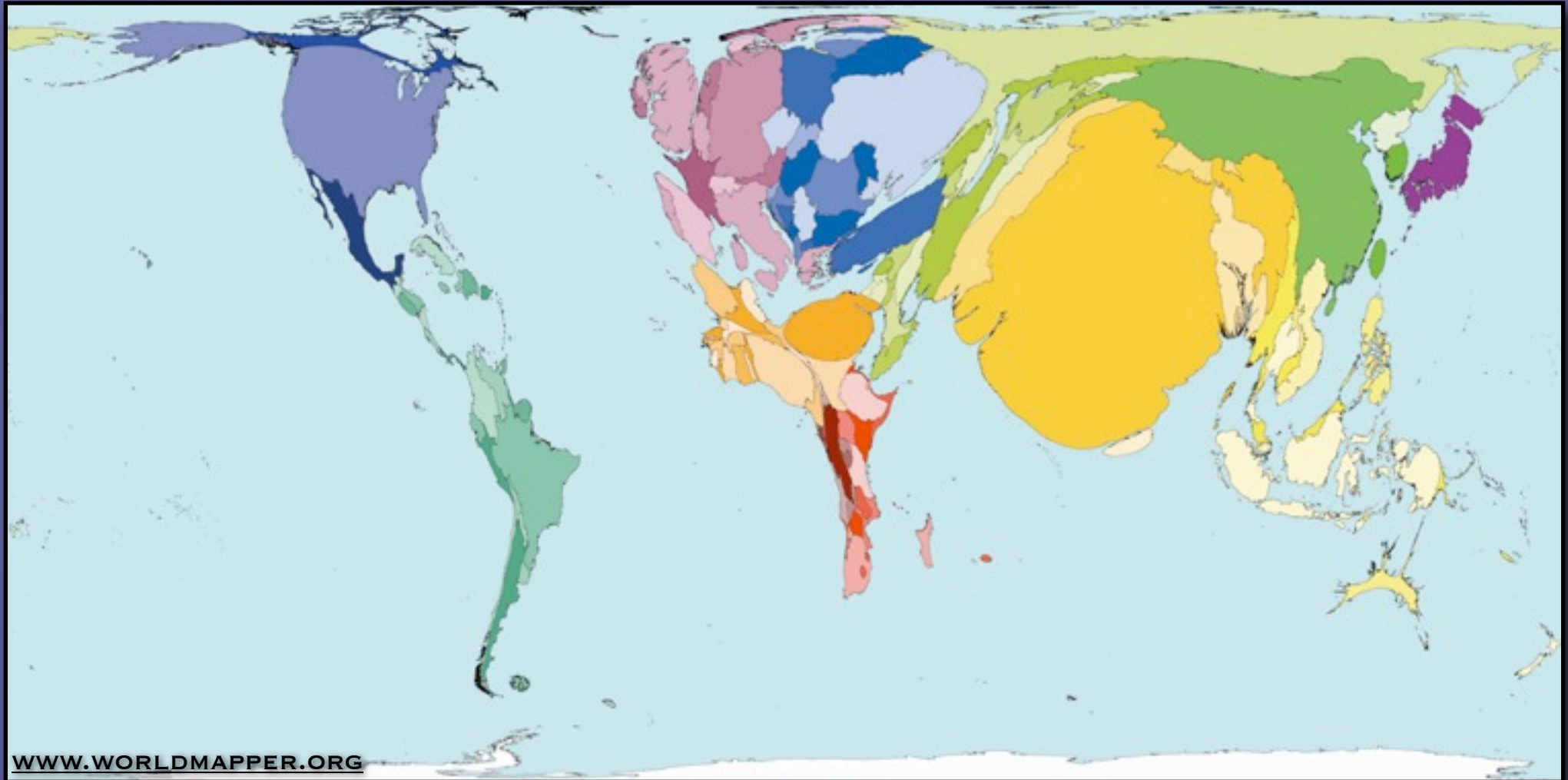
# DISCLOSURE

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





Investing in our future  
**The Global Fund**  
To Fight AIDS, Tuberculosis and Malaria

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Who We Are

Saving Lives

Grant Portfolio

Applicants and Implementers

Media Center

**The Global Fund to Fight AIDS, Tuberculosis and Malaria**, an international financing institution, invests the world's money to save lives. To date, it has committed US\$ 15.6 billion in 140 countries to support large-scale prevention, treatment and care programs against the three diseases.

- **HIV/AIDS**  
Over 2.3 million people on ARV
- **TUBERCULOSIS**  
5.4 million people under DOTS
- **MALARIA**  
88 million bednets distributed



## INNOVATING FOR IMPACT

Global Fund launches the Affordable Medicines Facility-malaria (AMFm)

### News Room

Global Fund Board appoints Minister of Health of Ethiopia as Chair  
[\[...\]](#) 10/Jul/2009

Global Fund investments support AIDS treatment for 2.3 mill. people  
[\[...\]](#) 08/Jul/2009

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### Grant Portfolio



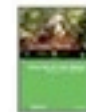
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Caceres, 30 March - 1 April

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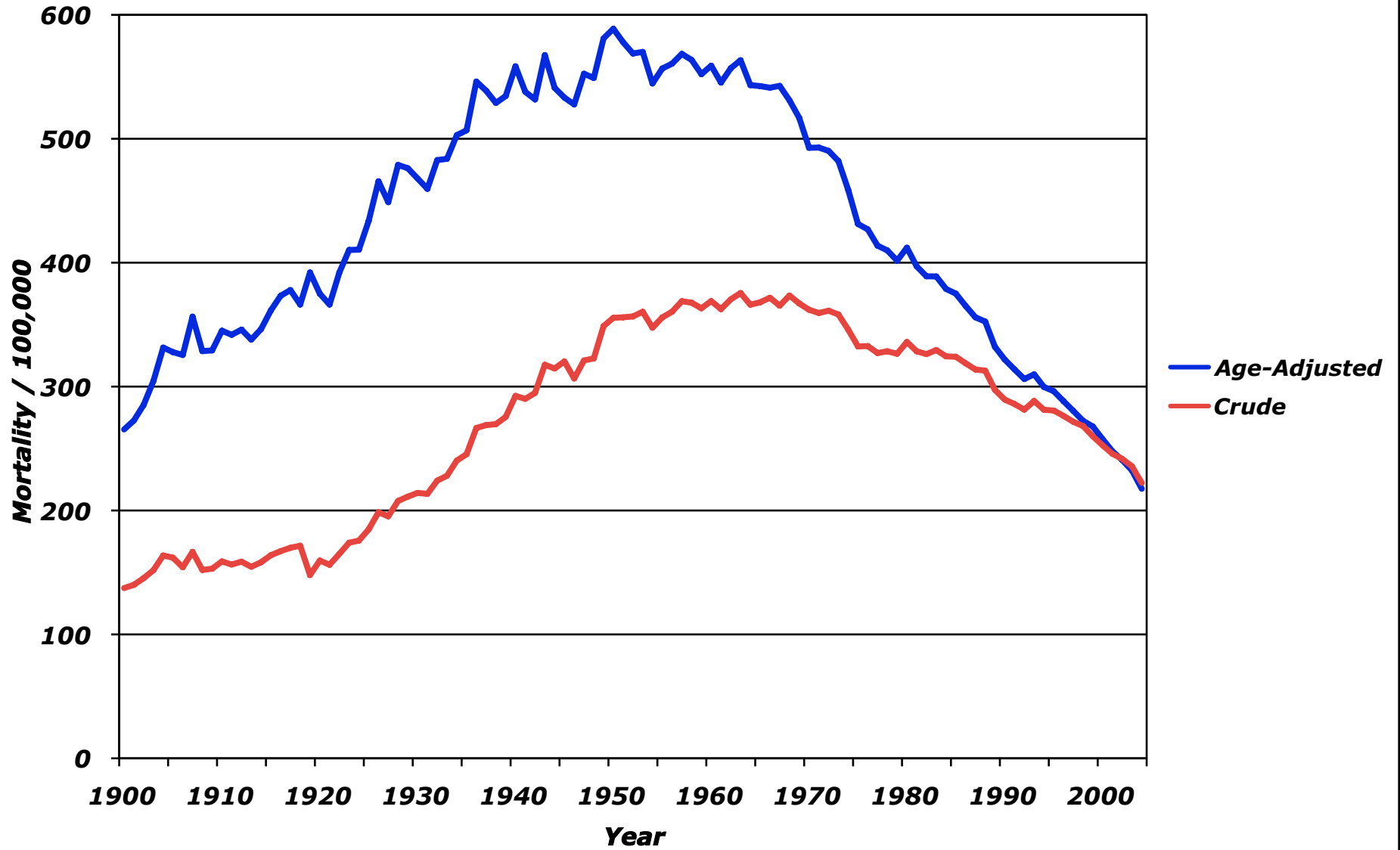
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Painting by Frank Netter, M.D. of man suffering from angina pectoris, chest pain due to coronary artery disease, removed due to copyright restrictions.

Photo of coronary angioplasty removed due to copyright restrictions.

# THE BEST RX FOR AMI IS PCI? HOW DO WE KNOW?

## ***Mortality from Diseases of the Heart***



"I'm going to grow  
a hundred  
years old!"

...and possibly she may—for the amazing strides  
of medical science have added years to life expectancy

It's a fact—a warm and wonderful fact—that this five-year-old child, or your own child, has a life expectancy almost a whole decade longer than her mother's, and a good 10 to 20 years longer than that of her grandmother. Not only the expectation of a longer life, but of a life by her health. Thank medical science for that. Thank your doctor and thousands like him... taking everybody, along with little or no jolting suspensions... that you and yours may enjoy a longer, better life.



According to a recent Nationwide survey:  
**More Doctors smoke Camels**  
*than any other cigarette!*

NOT ONE but three outstanding independent research organizations conducted this survey. And they asked not just a few thousand, but 101,007, doctors from coast to coast to name the cigarette they themselves preferred to smoke.

The answers came in by the thousands... from general physicians, diagnosticians, surgeons—yes, and some and others specialists too. The most-named brand was Camel.

If you are not now smoking Camels, try them. Compare them critically. See how the full, rich flavor of Camel's choice tobacco suits your taste. See how the real richness of a Camel suits your throat. Let your "T-Zone" tell you just right.



THE "T-ZONE" TEST WILL TELL YOU



The "T-Zone"—T for throat and T for throat—your own throat is your own throat. Only your own throat can tell you what your throat likes to get. And it affects your throat. On the back of the cigarette of many, many others of yours, we believe Camels will not lose "T-Zone" to a "T."

**CAMELS** *Coastlier  
Tobaccos*

DO YOU INHALE?



"Everybody's  
doing it!"

7 out of 10 smokers inhale knowingly—  
the other 3 inhale unknowingly

DO you inhale? 7 out of 10 smokers know they inhale. The other 3 inhale without realizing it. Every smoker inhales—in some part of the smoke he or she draws out of a cigarette.

Do you inhale? Of course you do! Lucky Strike has dared to raise this vital question... because certain impurities contained in even the finest, richest tobacco leaves are removed by Lucky's famous toasting process. Lucky's

ground-toasting process. Only Luckies have it!

Do you inhale? More than 20,000 physicians, after Luckies had been furnished them for tests, basing their opinions on their smoking experience, stated that Luckies are less irritating to the throat than other cigarettes.

"It's toasted"

Your Protection  
against irritation—against cough



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RISK FACTORS

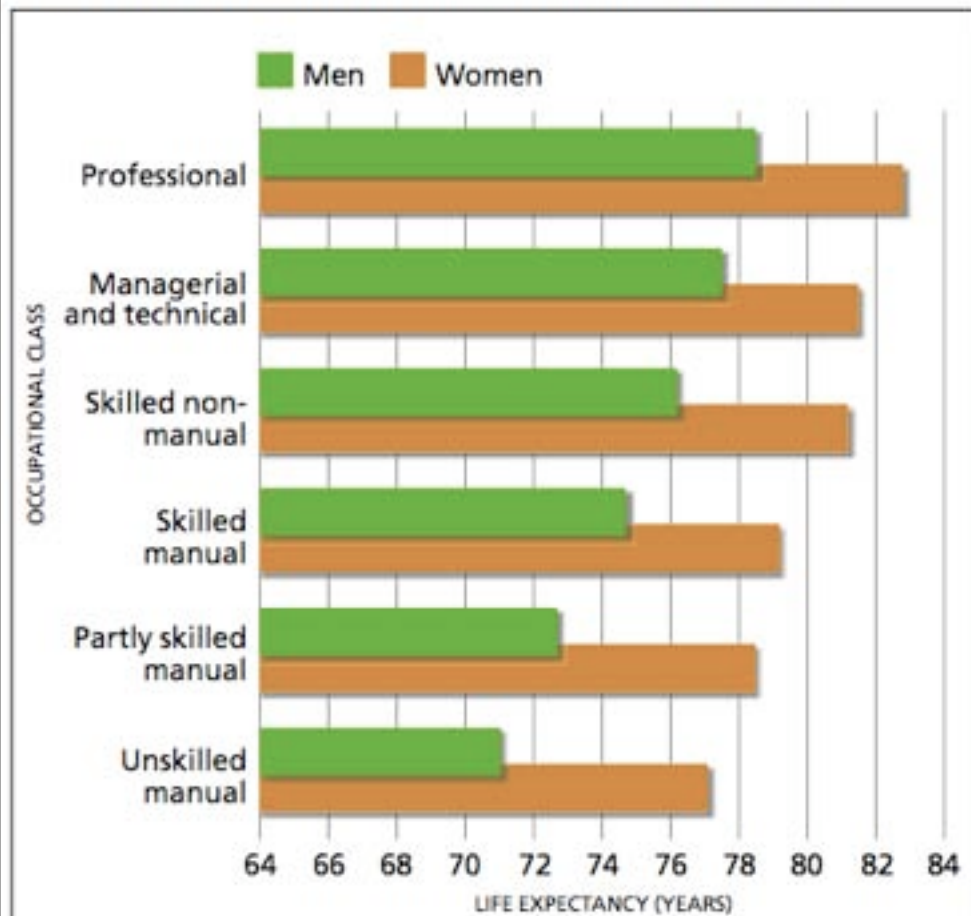
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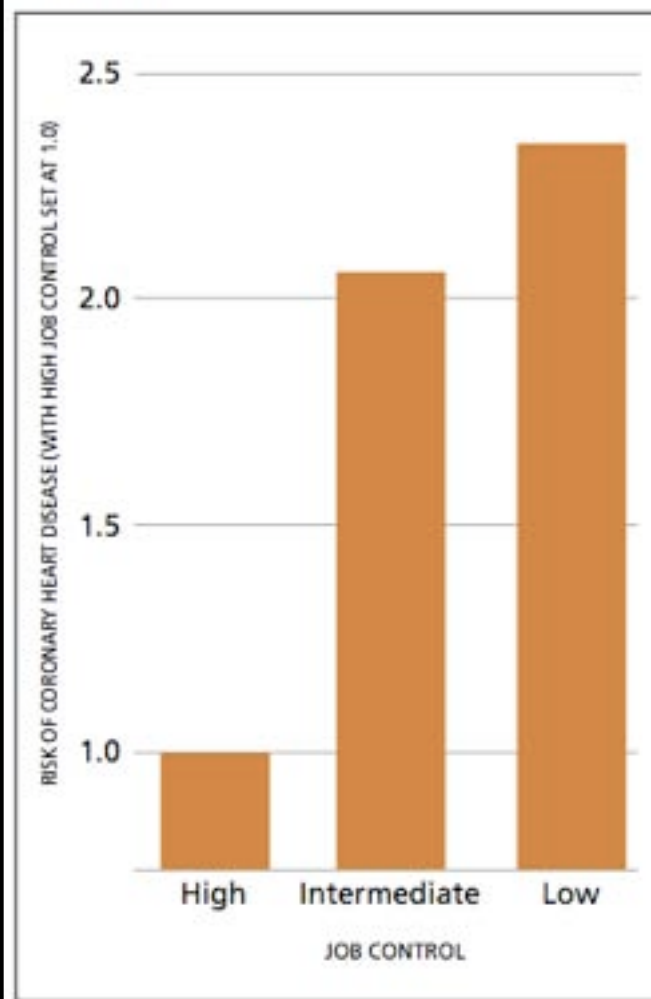


# OTHER RISKS?

**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?



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**DO NOT FEEL STRESS, OR CANNOT HANDLE IT**

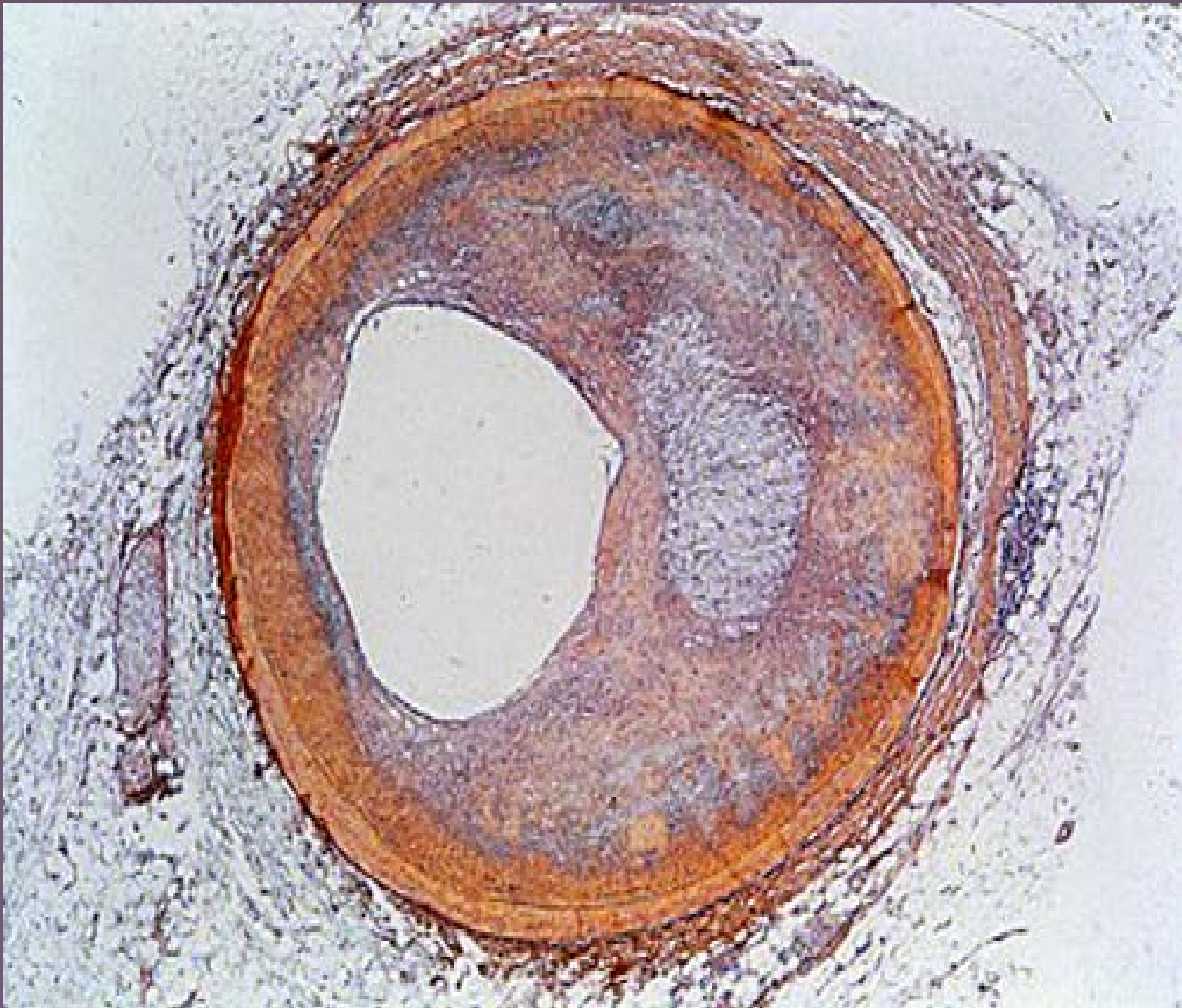
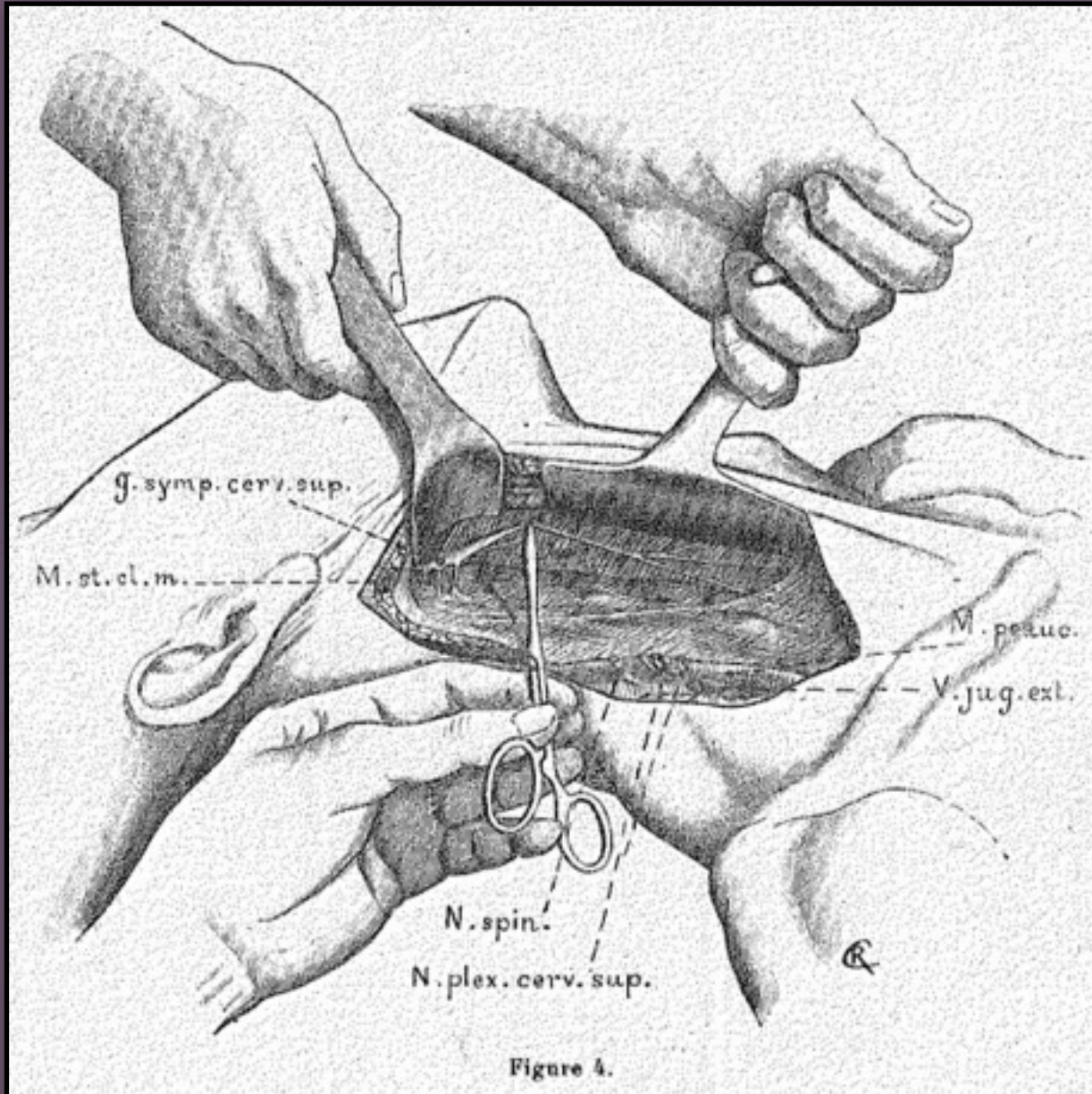


Photo courtesy the National Heart, Lung, and Blood Institute.

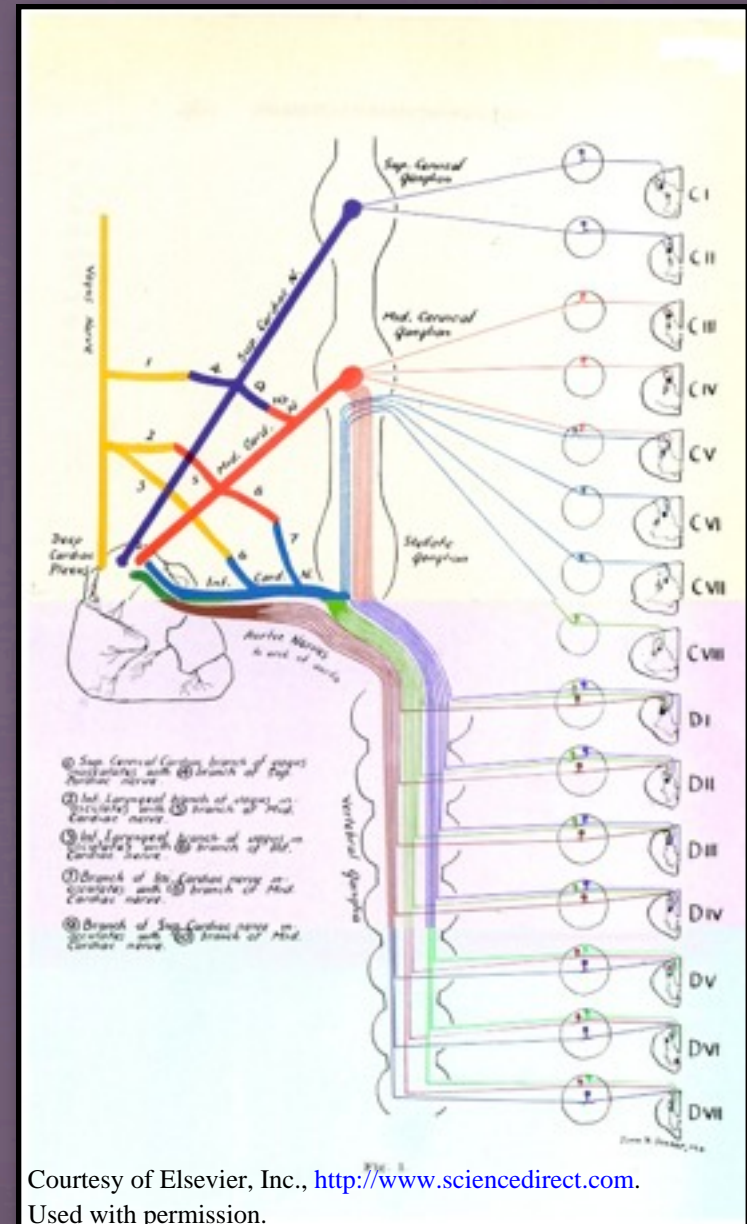
# HOW TO TREAT CORONARY ARTERY DISEASE?

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).



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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)

Excerpts from New England Journal of Medicine removed due to copyright restrictions.

For complete article, see Blumgart, Herrman L., A. Stone Freedberg, and George S. Kurland. "Treatment of Incapacitated Euthyroid Cardiac Patients by Producing Hypothyroidism with Radioactive Iodine."

*New England Journal of Medicine* 245, no. 3 (1951).

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.

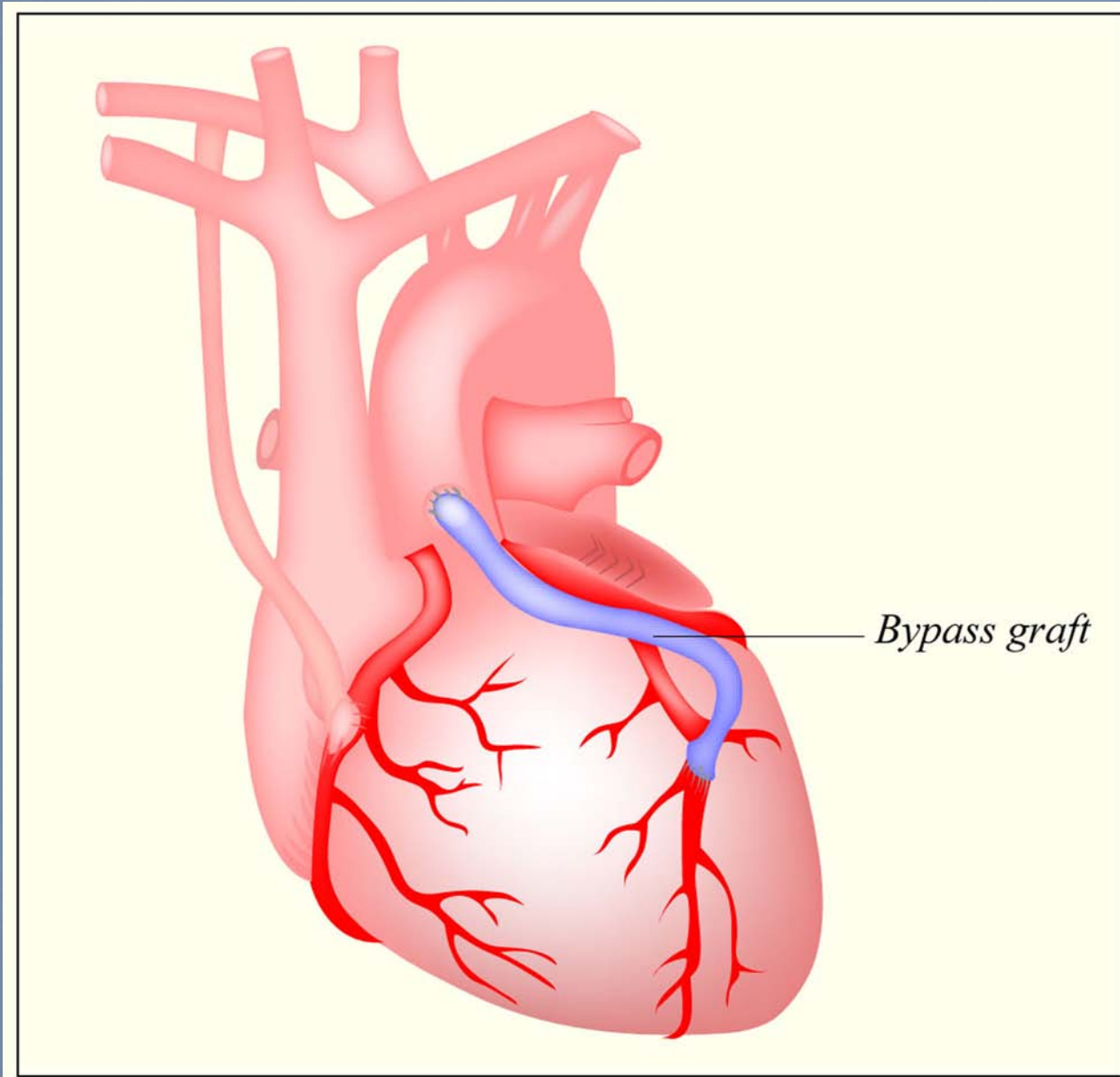


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Adapted from Cleveland Clinic.

# 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).



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?**

## Cerebral Damage during Open Heart Surgery

by

R. M. BASS  
Dewey Reed 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—at 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 haemodynamic 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, antifistul, rubber dust from the pump tubing or cell debris from blood damage, for none has ever been found in the fillets; nor has foreign material or fat been detected in brain tissue examined at post-mortem. The absence of obvious mechanical or biochemical causes 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 complicate making 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 (electrolyte 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. Reprecipitation 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, 30 per cent of the volume of the potential embolus—its O<sub>2</sub> content—will be taken up by the reduced haemoglobin leaving 60 per cent as nitrogen. The body is already fully saturated with nitrogen.

Evidence 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 structures due to shearing also occurs if the pumps are set too tightly. If the pump setting is just non-reversible the constriction, 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

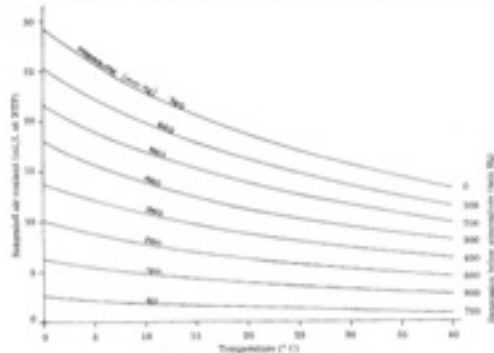


Fig. 1. Approximate solubility of air in water.

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# COMPLICATIONS OF CARDIAC SURGERY

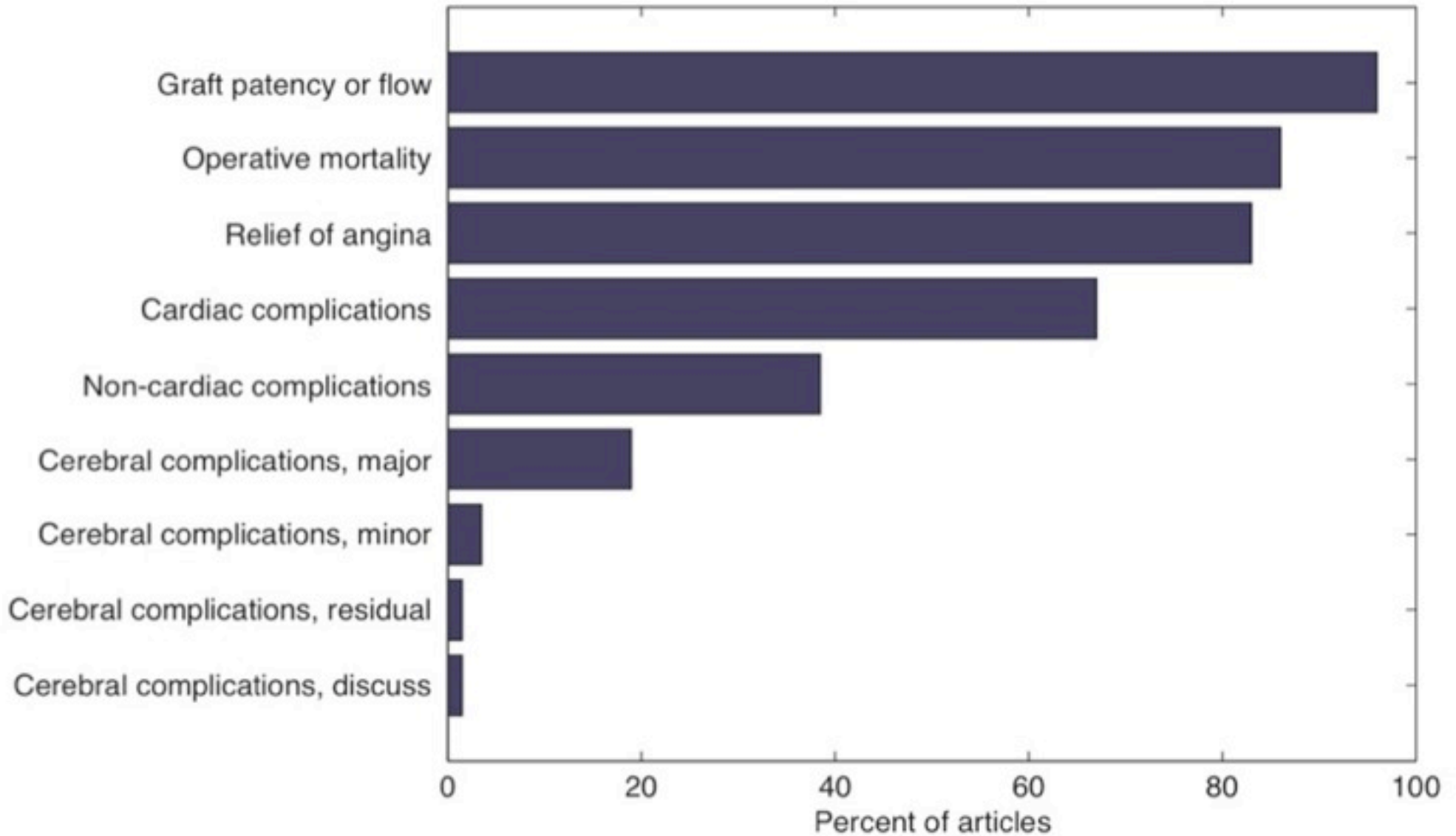
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For complete article, see Gilman, Sid. "Cerebral Disorders After Open-Heart Operations." *New England Journal of Medicine* 272, no. 10 (1965).

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Topics mentioned in early CABG outcomes reports, 1968-1973 (n = 200)



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**“PUMP HEAD”?**



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



Image courtesy [www.genome.gov](http://www.genome.gov).

# ANGIOPLASTY

Angiography photo of oculostenotic reflex removed  
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# THE “OCULO-STENOTIC REFLEX”

## A COMPULSION TO TREAT?

# PLAQUE RUPTURE

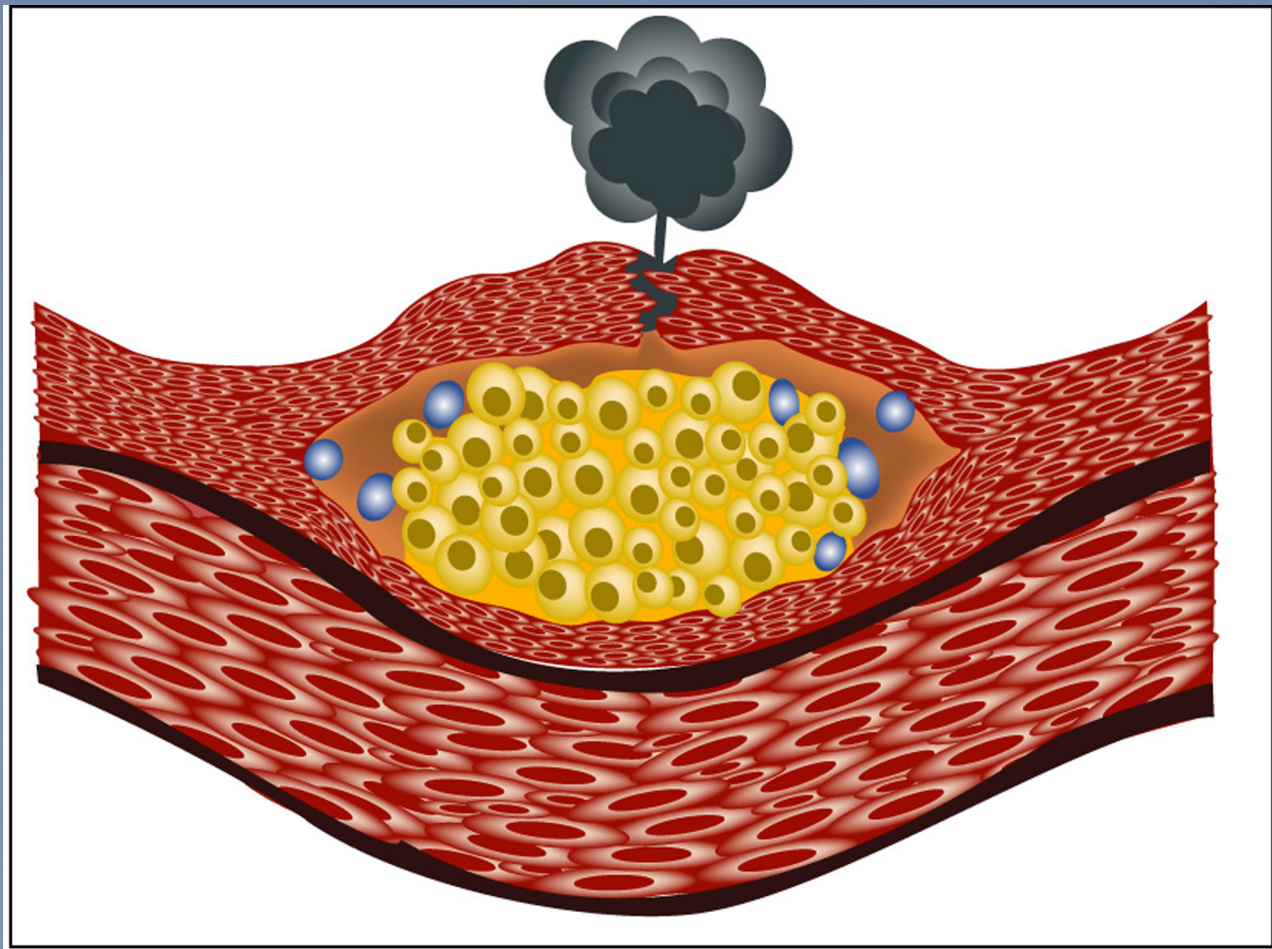


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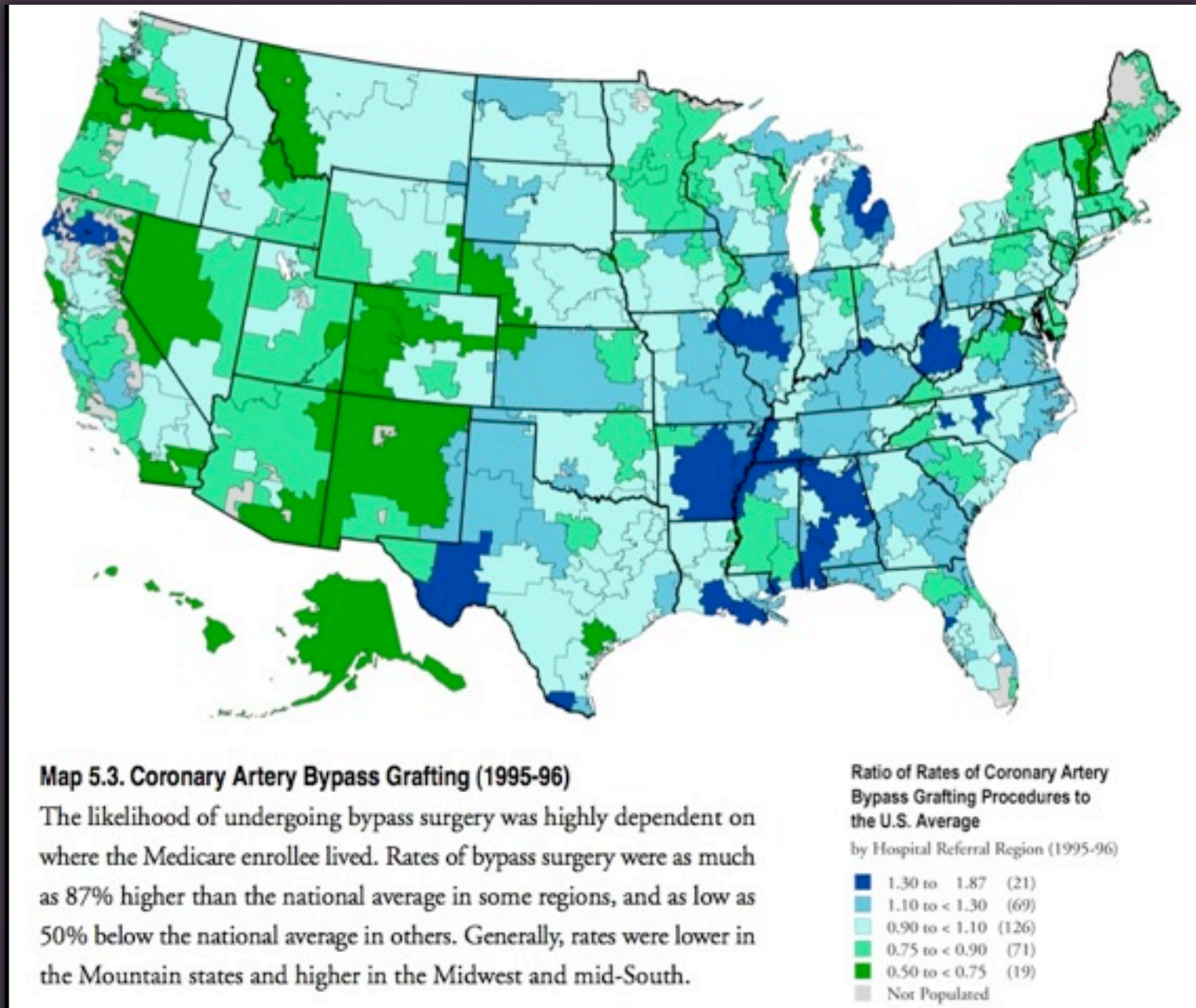
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# DISEASE MODELS AND TREATMENTS

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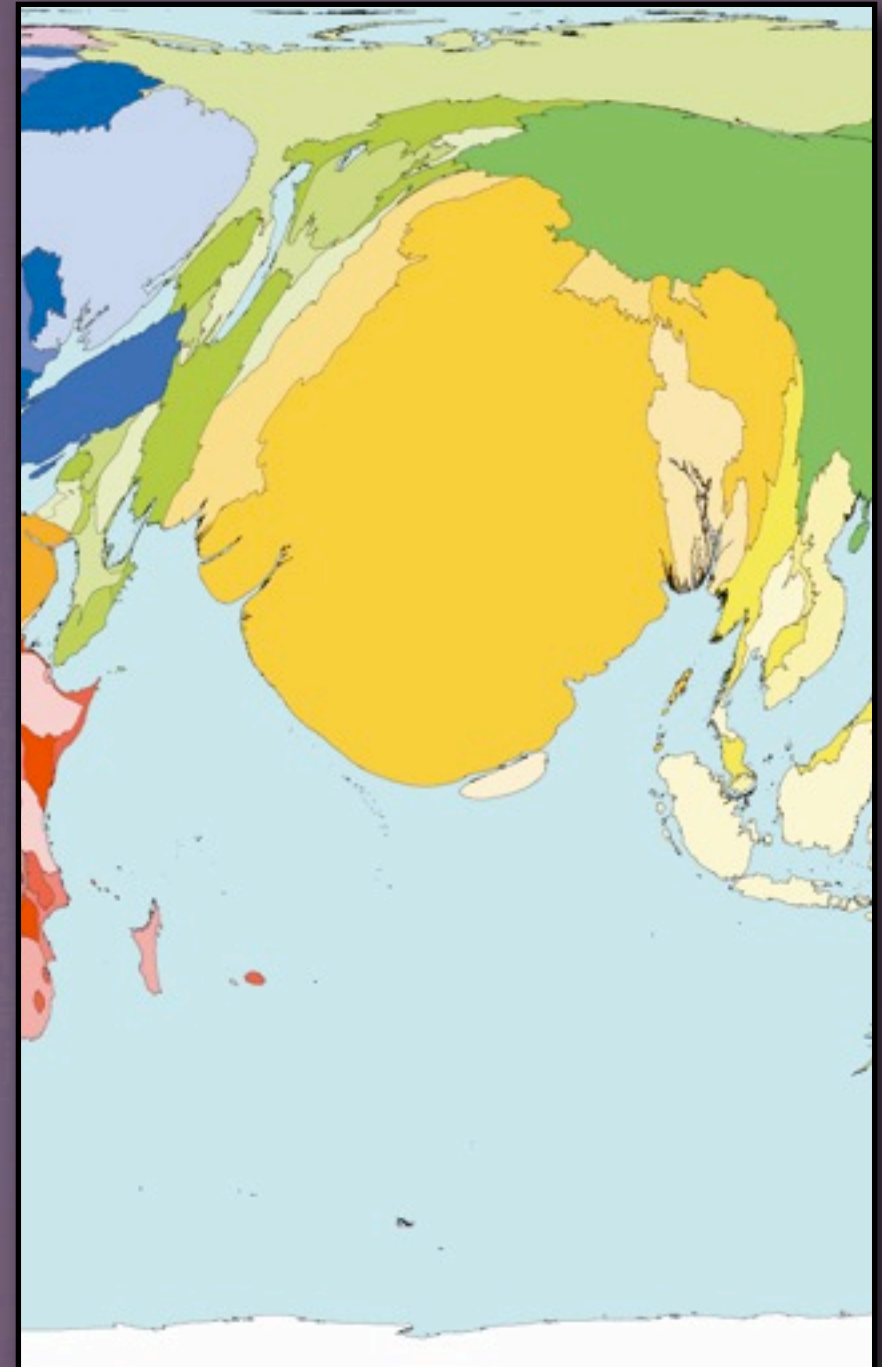
**WHAT SHOULD WE DO?**

# UNWARRANTED VARIATION?



● **WHY HAS THERE BEEN SO LITTLE ATTENTION?**

● **WHAT IS AN APPROPRIATE RESPONSE?**



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