INFORMED DECISION MAKING TO EMPOWER PATIENTS AND DOCTORS FOR THE BEST QUALITY CARE

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Special thanks to Professor Simon Capewell, Professor Sir Muir Gray, Professor David Newman

Efficient Health Care Requires Informed Doctors and Patients

Seven sins that contribute to lack of knowledge

- Biased funding of research (research funded because it is likely to be profitable, not because it is likely to be beneficial for patients)
- Biased reporting in medical journals
- Biased patient pamphlets
- Biased reporting in the media
- Commercial Conflicts of interest
- Defensive medicine
- Medical curricula that fail to teach doctors how to comprehend and communicate health statistics.

G. Gigerenzer, J.A Muir Gray. Better Doctors, Better Patients, Better Decisions, Envisioning Healthcare 2020,

Financial Conflicts of Interest/Culture to do More

- Financial influence of individual doctors to earn more based upon the number of investigations and procedures can sometimes put profits before patients
- One US Cardiologist admitted to ordering $19 million dollars worth of unnecessary investigations and procedures. (tip of the iceberg?)
- Fee for service model in US health system contributes to over use.
- In the UK “payment by results” is often “payment by activity”
- Unnecessary coronary stenting estimated to cost US health care $2.4 billion dollars a year (ACC Criteria -11.6% inappropriate, 38% “uncertain appropriateness”)
- Large and accepted body of evidence that stenting for stable coronary disease does not improve prognosis- multiple RCTs
- 88% of patients believed they were having it done for that very purpose
- 43% of Cardiologists said they would still go ahead and do the procedure even if they felt it would NOT benefit the patient
- Other drivers : technological imperative, asymmetry of information between doctor and patient and demand?

Technological Drive

Intra-Aortic Balloon Pumps

- Designed for use in cardiogenic shock complicating myocardial infarction
- Decades of use based upon industry sponsored Observational studies
- £40,000 per pump, catheter per patient £800
- 140,000 used worldwide
- Financial costs and potential harm to patient (stroke, haematoma, kidney failure, limb amputation)
- RCT – No improvement in reducing mortality at 30 days or 1 year

Thrombectomy Catheter

- Routinely used for past few years
- Safe but recent RCT revealed no benefit for reducing recurrent heart attack, mortality or stent thrombosis.
- 2012 total cost of using device in NHS approximately £700,000!
- Can we improve system that allows introduction of new devices/technology for greater value to minimise harms? More transparency with patients/informed consent?

BMJ

BMJ 2013;347:f5741 doi: 10.1136/bmj.f5741 (Published 24 September 2013)

OBSERVATIONS

FROM THE HEART

Too much angioplasty

Stenting offers no prognostic benefit over drugs in stable coronary disease

Aseem Malhotra *interventional cardiology specialist registrar, Royal Free Hospital, London*

Often a gulf exists between cardiologists' intellectual understanding of the available evidence and their clinical practice. Emotional and psychological factors, such as fear of untreated stenosis causing cardiac events, and pressure from patients who may not fully understand the heterogeneity and complexity of coronary disease, can influence decision making towards intervention. In one study 88% of patients undergoing a procedure for stable angina believed that angioplasty would prevent a myocardial infarction, and, given various scenarios, 43% of cardiologists said that they would go ahead with PCI even if they thought it would not benefit the patient.[9]

Much of clinical medicine is "palliative," and it is justifiable to

Invited Commentary

The Elephant in the Room
The Whole Truth About Coronary Stents

Aseem Malhotra, MBChB, MRCP

Given its cost and commonality, the appropriate application of percutaneous coronary intervention (PCI) in treating coronary artery disease is justifiably a health care policy priority. Understanding the limitations of the subjective assessment and treatment of coronary stenosis through coronary angiography alone has led to many changes, including greater incorporation of stress testing and intracoronary imaging devices into the cardiac catheter laboratory in recent years. Routine use of fractional flow reserve (FFR) (where a sensor-equipped guidewire is passed across a coronary lesion to assess intracoronary hemodynamics) and intravascular ultrasonography (IVUS) (where a miniature ultrasonographic probe

One could infer from the study by Fröhlich et al[5] that the subjective decision-making process by the interventional physician to treat lesions from their coronary angiographic appearance alone still has merit in comparison with an FFR-guided or IVUS-guided strategy for mortality. However, the decision by the interventionalist to incorporate FFR may have led to overtreatment of lesions purely based on subjective angiographic severity, which may have otherwise been proven to be negative for ischemia with FFR. For example, a lesion that may visually be estimated to be 80% stenosed and intervened on with angioplasty may not actually have functional significance. Such bias may also apply in treating the least tech-

More Informed Consent Can Reduce Potential Harms

- Would making it mandatory on the consent form that stents do not improve prognosis help to reduce patient anxiety, reassure of the benefits of medical therapy and encourage a more informed discussion about equally if not more important lifestyle changes?

- Reduce potential harm of a procedure that still carries a 1% risk of heart attack, stroke or death.

- When patients were told the lack of prognostic benefit for PCI, only 45.7% elected to go ahead with the procedure versus 69.4% who were not explicitly given this information

Rothberg MB, Scherer L, Kashef M, et al. The Effect of Information Presentation on Beliefs About the Benefits of Elective Percutaneous Coronary Intervention. *JAMA Intern Med.* 2014;174(10):1623-1629.

More is Not Better!

US regions with higher utilisation and expensive care reveal slightly worse mortality outcomes, lower perceived access, and less patient satisfaction

(Fisher ES, Wennberg DE, Stukel TA, Gottlieb DJ, Lucas FL, Pinder ÉL. The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care. Ann Intern Med. 2003;138:288-298)

- Greater frequency of physician visits
- More frequent use of specialist consultations
- More frequent tests
- Greater use of hospital and intensive care spending in high spending regions

(Fisher ES, Wennberg DE, Stukel TA, Gottlieb DJ, Lucas FL, Pinder ÉL. The Implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care. Ann Intern Med. 2003;138:273-287)

(End of life care: Of 1.8 million elderly beneficiaries of fee for service US medicare who died in 2008 ,31.9% underwent an inpatient surgical procedure during the year before death, 18.3% underwent a procedure in their last month of life and 8% underwent a procedure in their last week of life)

“ Getting beyond the more is better assumption will require a national debate on the limitation of medicine’s power to heal and cure and on the quality of care at the end of life.” Jack Wennberg

Statistical Risk and health illiteracy

- Inability to understand health statistics amongst lay public perhaps not surprising
- Doctors may find themselves having to curb unrealistic expectations of patients who may misunderstand media reports or find reliable information on the internet on whether to attend screening.
- In 1995 the British Committee on the Safety of Medicines reported that third generation oral contraceptive pill doubled the risk of thrombosis, therefore increasing the risk 100%- extensively reported in the media.
- Reality was an increase in risk from 1 in 7000 to 2 in 7000, an absolute risk increase for an individual of 1 in 7000.
- Estimated that as a result of pill scare 13,000 additional abortions took place the following year in England and Wales, costing the NHS £4-6 million.

Doctors understanding of health statistics- a risk factor for misinformation?

- Many doctors do not understand health statistics and therefore cannot evaluate the evidence for or against a treatment.
- In a study of 150 gynaecologists, one third did not understand the meaning of a 25% risk reduction created by mammography screening
- Most believed that if all women were screened 25% or 250 fewer women out of every 1000 would die of breast cancer
- Best evidence base from a Cochrane analysis of randomised studies involving 500,000 women would be 1 life saved per 2000 screened.
- Smaller study involving 20 gynaecologists 2 years after the Cochrane review which had concluded that it was unclear whether the benefits of mammography exceeded harms not a single one mentioned the risk of receiving an over diagnosis or over treatment despite evidence that for every 1 woman that does not die of breast cancer 10 would receive and over treatment as a result of screening.

Gigerenzer G, Gaissmaier W, Kurz-Milcke E, Schwartz LM, Woloshin S. Helping doctors and patients to make sense of health statistics. *Psychol Sci Public Interest* 2007; 8: 53-96

Misleading Health Statistics

- There are many ways of presenting a benefit. RRR, ARR or NNT
- Communicating relative risks as opposed to absolute risk or NNT (numbers needed to treat) can lead laypeople and doctors to overestimate the benefit of medical interventions.
- For example in high risk type 2 diabetics primary prevention with Atorvastatin 10mg, RRR 48% in stroke over 4 years.
- Reduces risk of suffering a stroke from 28 in 1000 to 15 in 1000 i.e 13 in 1000 or ARR od 1.3%
- NNT – need to treat 77 to prevent 1 stroke.
- Mismatched framing in medical journals compounds the issue.
- If treatment A reduces the risk of developing disease from 10 to 7 in 1000 but increases the risk of disease B from 7 to 10 in 1000 the journal article reports the benefit as a 30% risk reduction but the harm as an increase of 3 in 1000 or 0.3%!
- One third of articles in the Lancet, BMJ and JAMA between 2004 and 2006 used mismatched framing
- Such asymmetric presentation of data for benefits and harms is likely to bias toward showing greater benefits and diminishing the importance of the harms

WHO Bulletin 2009

“ It is an ethical imperative that every doctor and patient understand the difference between absolute and relative risks to protect patients against unnecessary anxiety and manipulation”

Gerd Gigerenzer, Director of Harding Center for Risk literacy, Berlin.

Case Study

- 49 year old type 2 diabetic and overweight man is reviewed in OPD 9 months following emergency coronary stenting
- Reports disabling and persistent chest pain in recent weeks which is atypical in nature for having a cardiac origin
- After checking there is no acute problem, no new ECG changes, blood tests normal, Cardiologist organises urgent repeat angiogram
- Coronary angiogram reveals the stent is patent, no flow limiting coronary stenosis as cause of pain.
- Patient reassured commenced on proton pump inhibitor (could this be acid reflux?)and discharged back to GP with routine out patient review planned in six weeks
- Patient is seen in Cardiology out patients six weeks later still complaining of disabling chest pain and also now mentions accompanying muscle aches. Wife is concerned its making him depressed. GP has referred him to a gastroenterologist.
- Patient advised to stop statin medication for 2 weeks on trial basis
- Returns to clinic 1 week later elated. “Thank you doctor-. After months of misery my pain has disappeared but now I am worried. My GP said “ you must never stop your statin or you could die!”

Has Over Emphasis on Medical Treatment Detracted from Addressing Lifestyle?

- 60% of the adult UK population are either overweight or obese
- 1 in 3 children in the same category –trends increasing
- Foresight report: If we do nothing 90% Of UK population overweight or obese by 2050
- Currently costing the NHS £6 billion/year > £50 billion
- Total cost of diabetes close to £20 billion; double by 2035
- NCDs (diet as a risk factor) have now overtaken under nutrition as the commonest cause of death worldwide
- Is obesity just the tip of the iceberg?

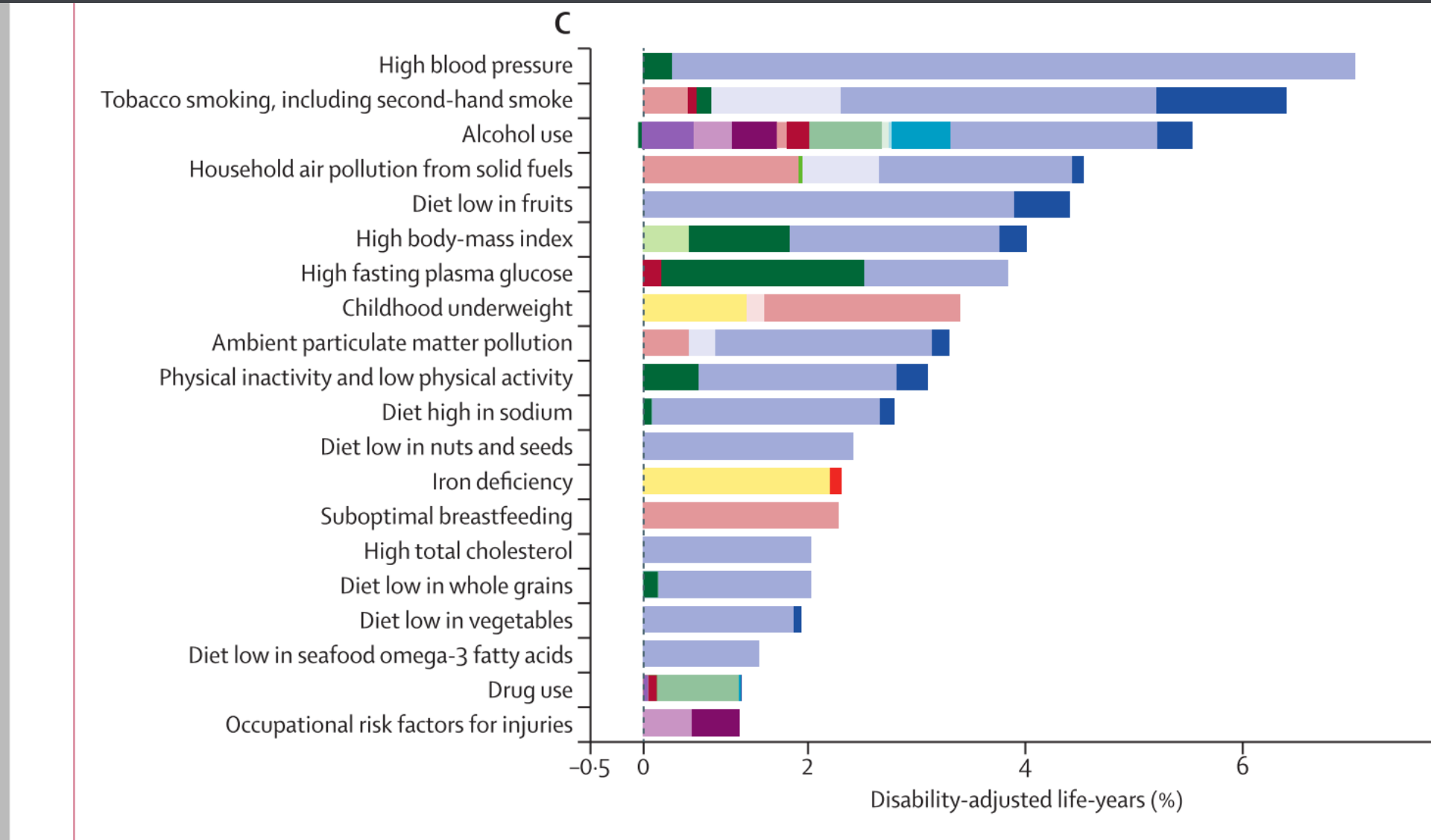
WHO Cardiovascular Disease -Key Facts

- CVDs are the number one cause of death globally: more people die annually from CVDs than from any other cause
- An estimated 17.3 million people died from CVDs in 2008, representing 30% of all global deaths. Of these deaths, an estimated 7.3 million were due to coronary heart disease and 6.2 million were due to stroke
- Low- and middle-income countries are disproportionally affected: over 80% of CVD deaths take place in low- and middle-income countries and occur almost equally in men and women
- The number of people who die from CVDs, mainly from heart disease and stroke, will increase to reach 23.3. million by 2030 CVDs are projected to remain the single leading cause of death
- Most cardiovascular diseases can be prevented by addressing risk factors such as tobacco use, unhealthy diet and obesity, physical inactivity, high blood pressure and diabetes.

Burden of disease attributable to 20 leading risk factors in 2010

expressed as a percentage of global disability-adjusted life-years

Global Burden of Disease Group. www.thelancet.com 2012 380 2245 (MEN & WOMEN)



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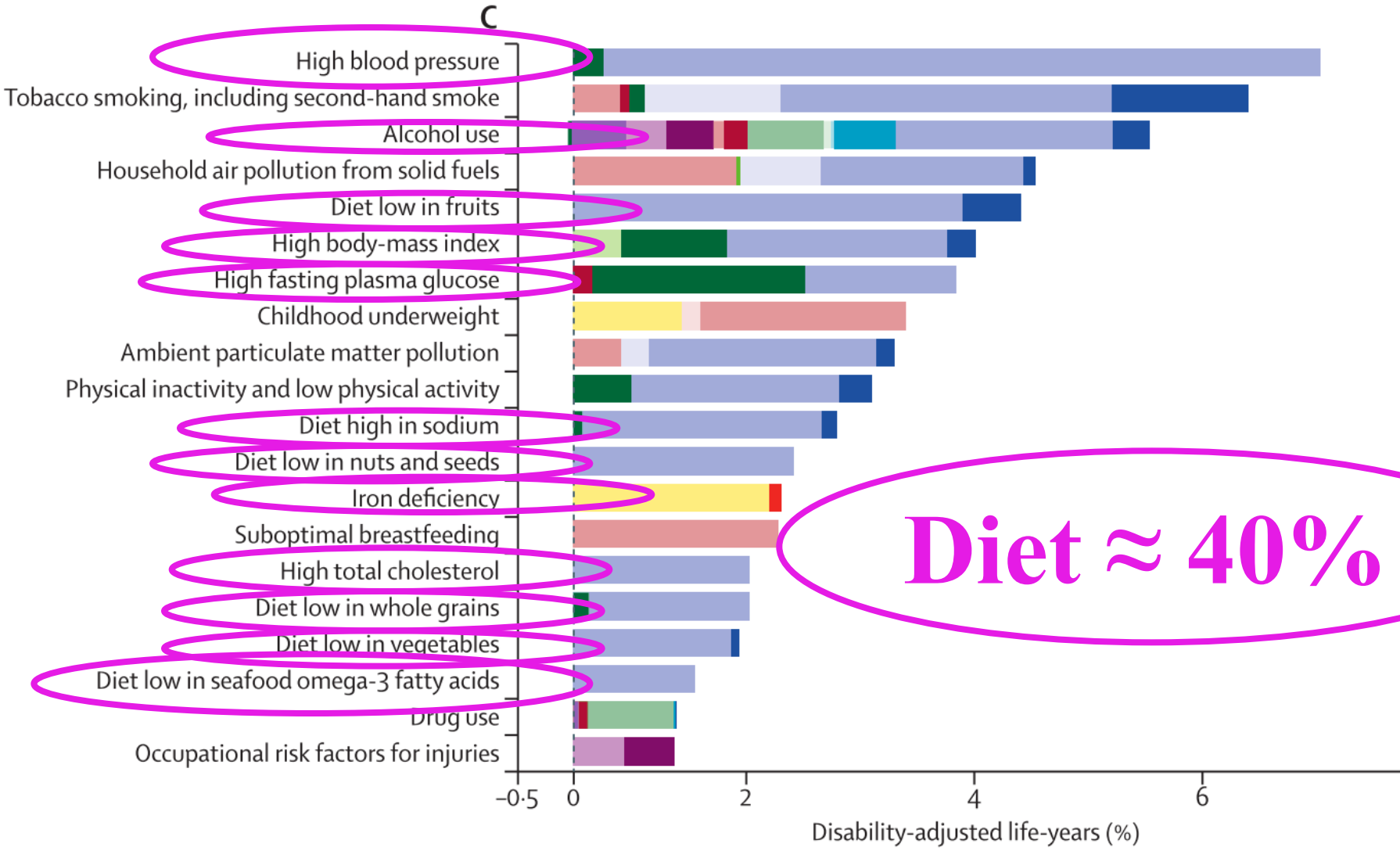
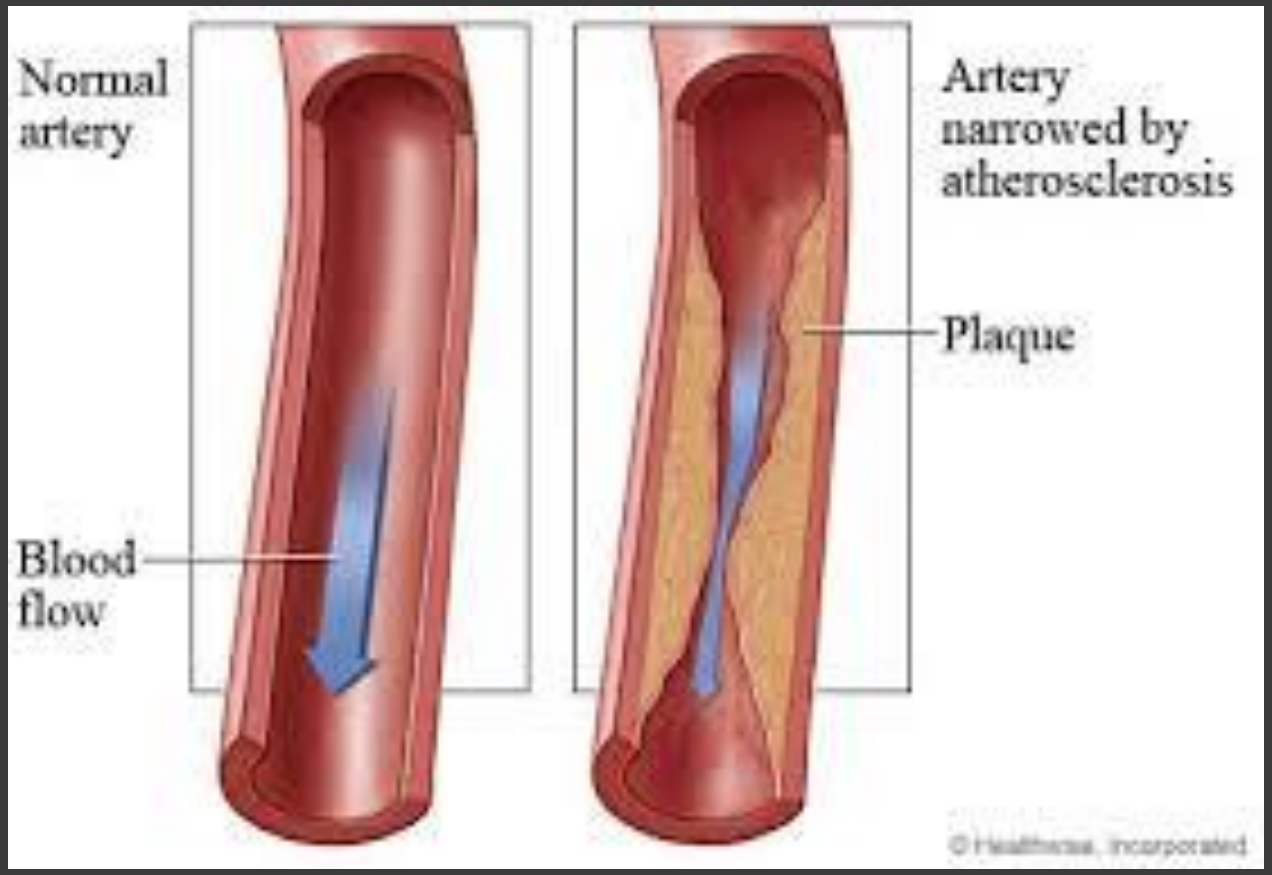
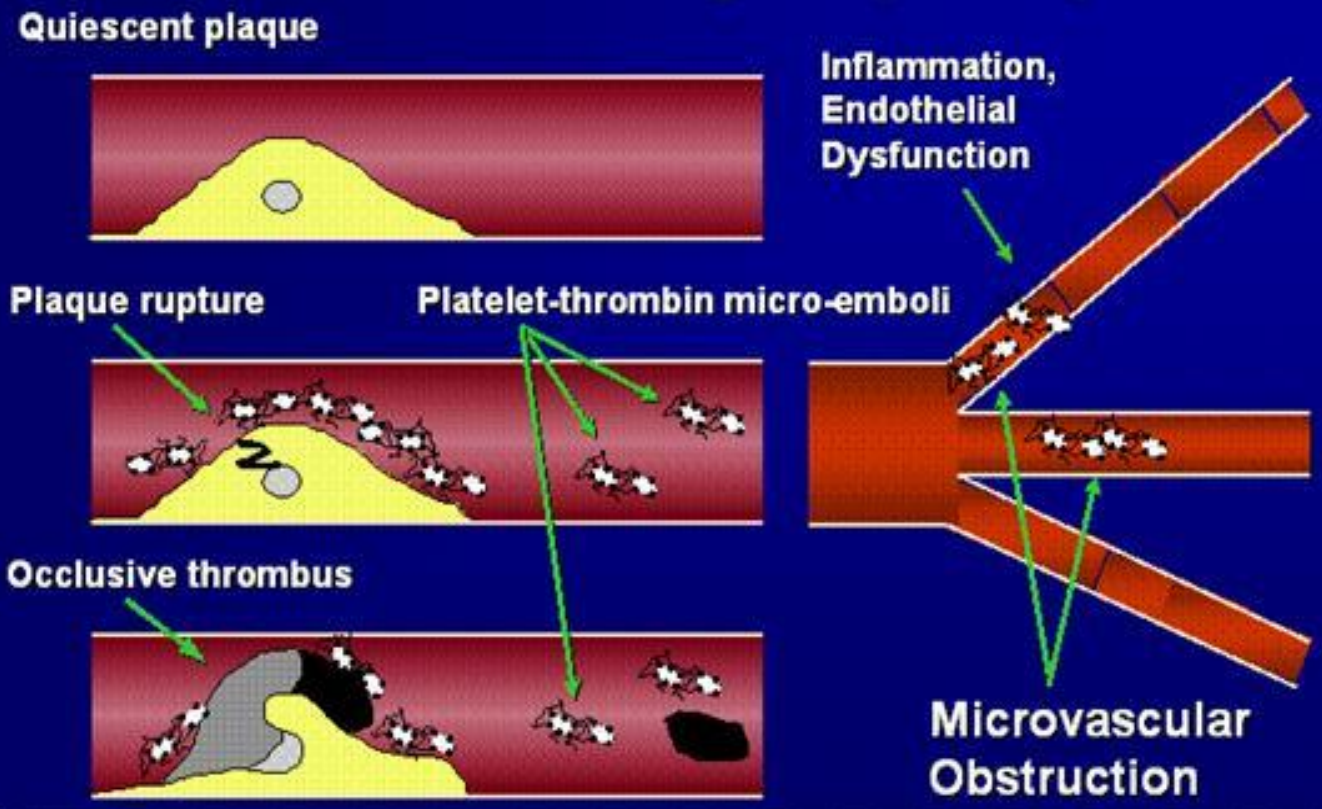



Normal artery
Blood flow
Artery narrowed by atherosclerosis
Plaque

Microvascular Obstruction with Troponin Elevation Following Plaque Rupture



Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

- *Newby & Ohman, JACC 2003*

Rapid Mortality Falls After Risk Factor Changes In Populations

- The underlying pathological process preceding most coronary and stroke events—normally takes many decades to progress.
- Arterial stiffening can be shown in children who are obese, and aortic fatty streaks are visible in some teenagers and young adults (Strong JP, Malcom GT, McMahan CA, et al. Prevalence and extent of atherosclerosis in adolescents and young adults: implications for prevention from the Pathobiological Determinants of Atherosclerosis In Youth Study. *JAMA* 1999; **281:** 727–35)
- Most cardiovascular events manifest after the age of 60
- Perception of a process that will progress slowly and reverse slowly if at all is WRONG!
- Extensive empirical and trial evidence shows that substantial reductions in mortality can occur within months of decreases in smoking, and within 1–3 years of dietary changes (Capewell S, O'Flaherty M. Can dietary changes rapidly decrease cardiovascular mortality rates? *Eur Heart J* 2011; published online March 2. DOI:10.1093/eurheartj/ehr049)

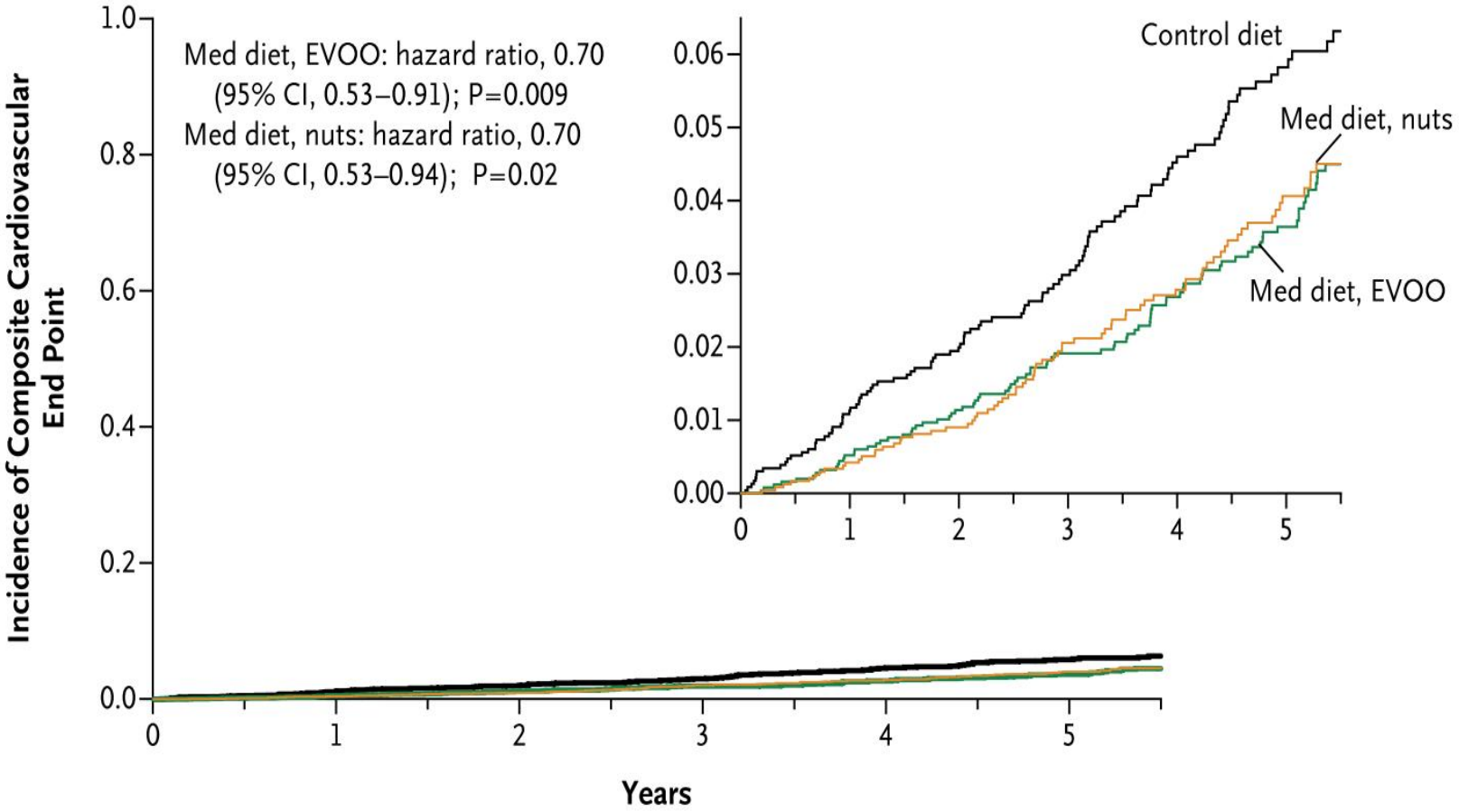
Rapid Mortality Falls Continued…

- Helena, Montana, USA- Smoke free legislation in 2002 led to 40% reduction in hospital admissions for Acute Coronary Syndromes following smoke free legislation within 6 months. Law was recinded and admissions for ACS returned to preceding levels.

- Smoke free legislation in Scotland 2006, 17% reduction in hospital admissions within a year and 6% fall in out of hospital cardiac deaths. Meyers DG, Neuberger JS, He J. Cardiovascular effect of bans on smoking in public places: a systematic review and meta-analysis. *J Am Coll Cardiol* 2009;**54:** 1249–55.

PREDIMED RCT: Primary prevention of CVD with a Mediterranean diet. Estruch et al NEJM 2013

A Primary End Point (acute myocardial infarction, stroke, or death from cardiovascular causes)

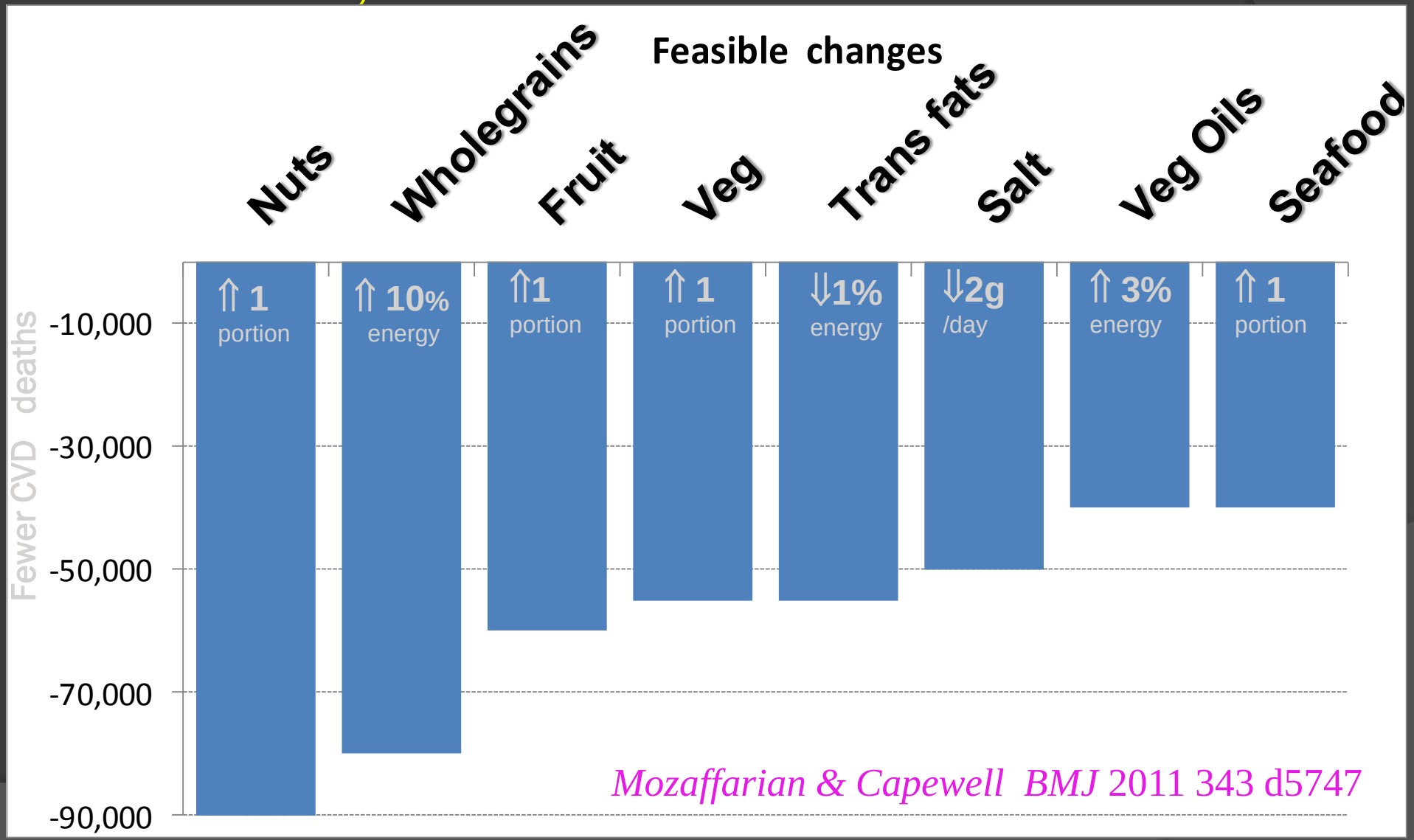


No. at Risk

Control diet	2450	2268	2020	1583	1268	946
Med diet, EVOO	2543	2486	2320	1987	1687	1310
Med diet, nuts	2454	2343	2093	1657	1389	1031

CVD mortality reductions with healthier US food policy options

US 2006 baseline: 810,000 *CVD deaths*



Mozaffarian & Capewell BMJ 2011 343 d5747

NNTs for Treatment of Heart Disease – Death- 5 Years

- Aspirin (high risk) 100
- Statins (high risk) 83

- Aspirin and statins (low risk) – infinity…

- Coronary stents during heart attack 40
- Coronary stents at any other time?
- MEDTERRANEAN DIET!!!! 30

- “ The preservation of the means of knowledge among the lowest ranks is of more importance to the public than all the property of all the rich men in the country” John Adams, 2nd US President, 1775.