Health and Illness in the Age of Genomics

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November 2010

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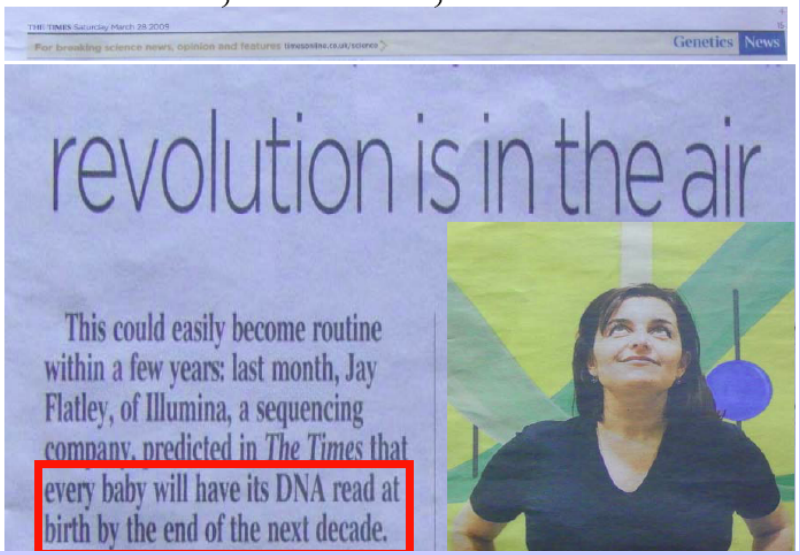
VISIONS OF THE FUTURE

In this new three-part series, leading theoretical physicist and futurist Dr Michio Kaku explores the cutting edge science of today, tomorrow, and beyond. He argues that humankind is at a turning point in history. In this century, we are going to make the historic transition from the 'Age of Discovery' to the 'Age of Mastery', a period in which we will move from being passive observers of nature to its active choreographers. This will give us not only unparalleled possibilities but also great responsibilities.

The Times, March 28, 2009



THE TIMES Saturday March 28 2009

For breaking science news, opinion and features timesonline.co.uk/science

Genetics News

revolution is in the air

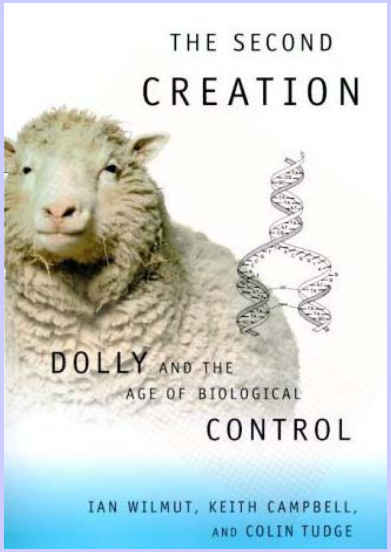
This could easily become routine within a few years: last month, Jay Flatley, of Illumina, a sequencing company, predicted in *The Times* that every baby will have its DNA read at birth by the end of the next decade.

2. THE BIOTECH REVOLUTION

Genetics and biotechnology promise a future of unprecedented health and longevity: DNA screening could prevent many diseases, gene therapy could cure them and, thanks to lab-grown organs, the human body could be repaired as easily as a car, with spare parts readily available. Ultimately, the ageing process itself could be slowed down or even halted.

But what impact will this have on who we are and how we will live? And, with our mastery of the genome, will the human race end up in a world divided by genetic apartheid?

The Age of Biological Control - Ian Wilmut (2000)



- "Until the birth of Dolly, scientists were apt to declare that this or that procedure would be 'biologically impossible'-- but now that expression …seems to have lost all meaning. In the 21st century and beyond, human ambition will be bound only by the laws of physics, the rules of logic, and our descendents' own sense of right and wrong. Truly, Dolly has taken us into *the era of biological control*"

- "This means that we can no longer assume that the biological itself' will impose limits on human ambitions. As a result, humans must accept much greater responsibility toward the realm of the biological, which has, in a sense, become a wholly contingent condition"

CONTINGENT

A. *adj.* …

2.

a. Liable to happen or not; of uncertain occurrence or incidence.

b. Incidental (*to*).

4. Happening or coming by chance; not fixed by necessity or fate; accidental, fortuitous.

5. Not determined by necessity in regard to action or existence; free. *Obs.*

6. Subject to or at the mercy of accidents; liable to chance and change.

7. *Metaph.*

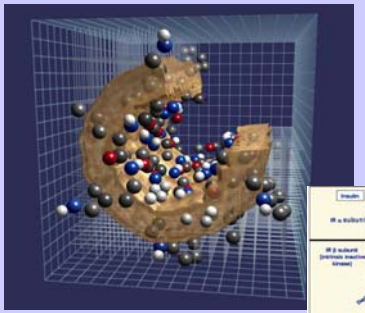
a. Not of the nature of necessary truth; true only under existing conditions.

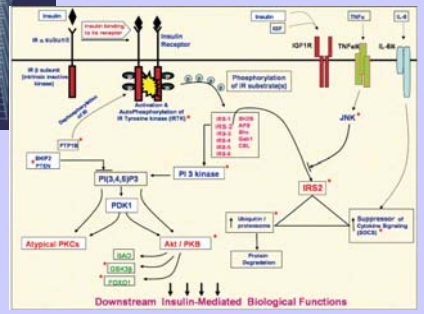
b. That does not exist of itself, but in dependence on something else.

c. Non-essential.

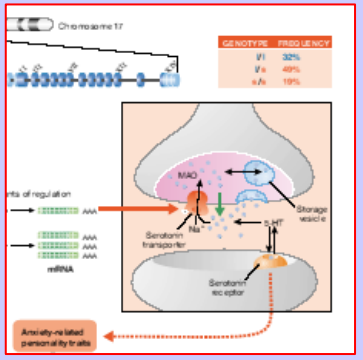
8. Dependent for its occurrence or character *on* or *upon* some prior occurrence or condition.

Biological control?





- Scientific hubris of course
  - much remains 'biologically impossible'
  - 'nature' says no as often as yes
- But points to a mutation in our very idea of life
  - Life as mechanism, bodies and brains as engineerable apparatus
  - Molecular gaze of biology
- Beyond the binary of the normal and the pathological
  - no-one is normal, normality and pathology explained in the same terms, no such thing as normal body, brain, genome, scan, aging…
- An age of control over our biology?
  - Biopprediction – to know and control our biofutures.



China overtakes India in drug testing

By Andrew Jack in London and Amy Yee in New Delhi, Published: August 27 2007 23:31

China has overtaken India as one of the fastest-growing locations for drug trials, in a fresh sign of the importance of the world's most populous country to the pharmaceutical industry.

An analysis by the Financial Times of data on www.clinicaltrials.gov, one of the most comprehensive websites where researchers register their studies, shows that China has 274 clinical trials under way, compared with 260 in India.

That site also indicates that China now has a cumulative total of 510 completed or ongoing trials compared with 471 in India, which had until recently been ahead on both measures. The trend reflects intensifying interest by the healthcare sector in China, which is growing rapidly as a result of rising income and expanding health coverage and is already forecast to be the world's fifth-largest pharmaceuticals market by 2010.

Daniel Vasella, chief executive of Novartis, the Swiss pharmaceutical company, warned earlier this month that he was likely to switch substantial future funding that could have gone to India to other countries, including China, because of a recent court ruling on patents.

As they seek to reduce the escalating costs and speed up the conduct of the clinical trials necessary to win regulatory approval for new medicines, drug companies are increasingly shifting tests from the US and western Europe to eastern Europe, Latin America and Asia.

India and China have both received increased attention by pharmaceutical companies in recent years, reflecting a strong medical infrastructure, substantially lower costs and the relative ease of recruiting patients with diseases under investigation – which allows trials to be launched more rapidly.

Last updated at: (Beijing Time) Thursday, March 11, 2004

China launches first biobank

China recently launched its first biobank, a database with information on people's medical history, lifestyle, occupation and blood sample for DNA analysis in Guangzhou, capital of South China's Guangdong Province.

The Kadoorie Biobank Study in China
中英合作慢性病前瞻性研究项目

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The Kadoorie Biobank Study in China (KBSC) is a prospective health study investiga
chronic diseases, such as stroke, heart disease, cancer, diabetes and chronic respira
513,000 people aged 30-79 were recruited from 10 areas across China. During the
participant consented to take part, had a blood sample taken, underwent physical e
completed a questionnaire. Participants will be closely monitored over the coming d
hospital admissions and deaths. More details about the study are available in About
the data and resources available, including biological samples, can be found in Resou

The KBSC is a collaborative project between the Clinical Trial Service Unit & Epidemi
(CTSU) at the University of Oxford and the Chinese National Center for Disease Cor
Beijing (China CDC). The study was set up with financial support from the Kadoorie
Hong Kong, and additional funding has come from the Wellcome Trust, the Medical
the British Heart Foundation. The study was previously called the Kadoorie Study of
(KSCDC).

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中国人群遗传多样性数据库
Genetic Diversity Database of Chinese Population

A brief introduction

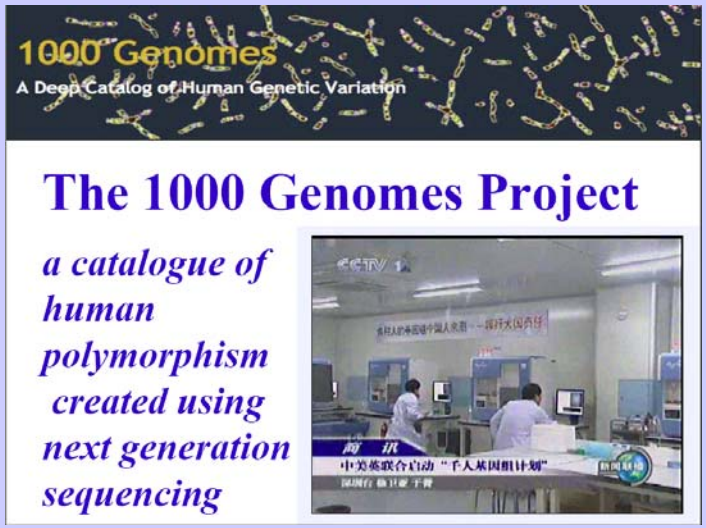
China is a country with long history and broad areas. The population of it is nearly 1,300,000,000 and is divided into 56 ethnic groups. Those minorities have various originates, settled areas, different languages, cultures and customs. Among of them, there are even several groups living isolated from others. Recent researches have found that genetic diversities between different groups are strong related to human health and diseases. Research on genetic diversity has become an important fields for a comprehensive understanding of human genome and its function. The research result is very significant for basic research in medical genetics, related fields with human health, individual identification in medical jurisprudence, human origin, evolution and migration.

Our country is well known as a nation with abundant human genetic resources. Genetic diversity between different groups has long been an important part in Chinese human genome research. Under the support of the government and the efforts that the scientists make, genetic diversity research in China has achieved great success. A lot of information and

"China Uncorks the Gene in a Bottle"

Far Eastern Economic Review 03/22/2001 by David Murphy

"So what has China achieved in the life sciences so fa
A good place to begin answering that question is th
Beijing Genomics Institute…"



nature Vol 456 | 6 November 2008 | doi:10.1038/nature07484

ARTICLES

The diploid genome sequence of an Asian individual

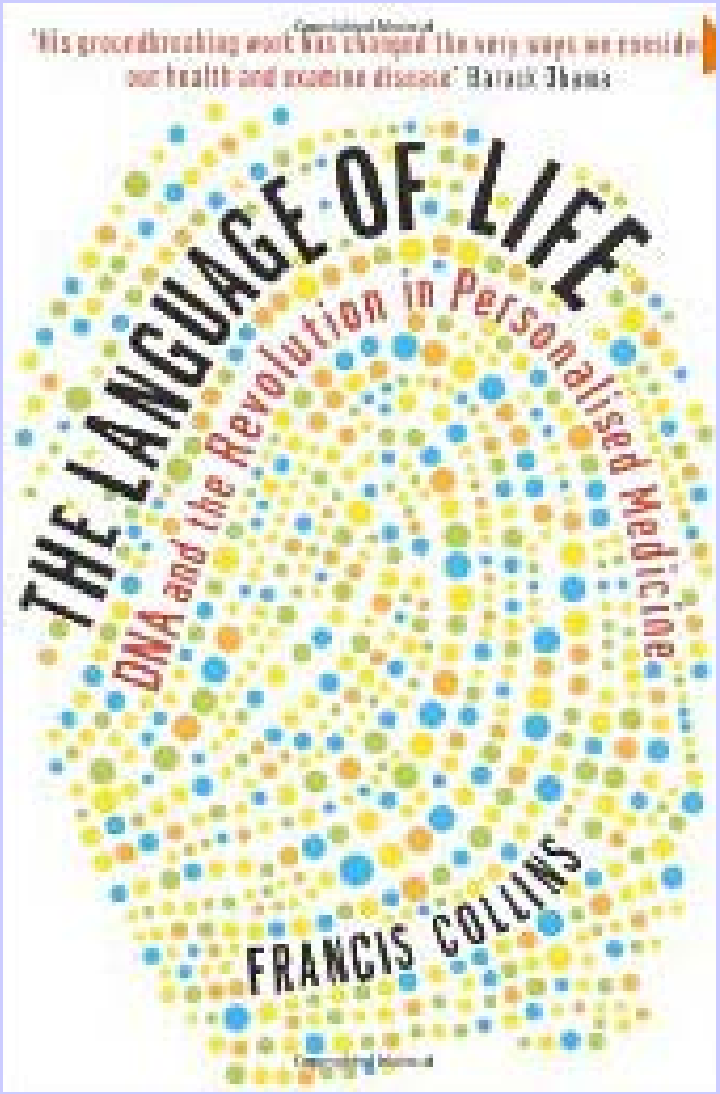
Jun Wang[1,2,3,4*], Wei Wang[1,3*], Ruiqiang Li[1,3,4*], Yingrui Li[1,5,6*], Geng Tian[1,7], Laurie Goodman[1], Wei Fan[1], Junqing Zhang[1], Jun Li[1], Juanbin Zhang[1], Yiran Guo[1,7], Binxiao Feng[1], Heng Li[1,8], Yao Lu[1], Xiaodong Fang[1], Huiqing Liang[1], Zhenglin Du[1], Dong Li[1], Yiqing Zhao[1,7], Yujie Hu[1,7], Zhenzhen Yang[1], Hancheng Zheng[1], Ines Hellmann[9], Michael Inouye[8], John Pool[9], Xin Yi[1,7], Jing Zhao[1], Jinjie Duan[1], Yan Zhou[1], Junjie Qin[1,7], Lijia Ma[1,7], Guoqing Li[1], Zhentao Yang[1], Guojie Zhang[1,7], Bin Yang[1], Chang Yu[1], Fang Liang[1,7], Wenjie Li[1], Shaochuan Li[1], Dawei Li[1], Peixiang Ni[1], Jue Ruan[1,7], Qibin Li[1,7], Hongmei Zhu[1], Dongyuan Liu[1], Zhike Lu[1], Ning Li[1,7], Guangwu Guo[1,7], Jianguo Zhang[1], Jia Ye[1], Lin Fang[1], Qin Hao[1,7], Quan Chen[1,5], Yu Liang[1,7], Yeyang Su[1,7], A. san[1,7], Cuo Ping[1,7], Shuang Yang[1], Fang Chen[1,7], Li Li[1], Ke Zhou[1], Hongkun Zheng[1,4], Yuanyuan Ren[1], Ling Yang[1], Yang Gao[1,6], Guohua Yang[1,2], Zhuo Li[1], Xiaoli Feng[1], Karsten Kristiansen[4], Gane Ka-Shu Wong[1,10], Rasmus Nielsen[9], Richard Durbin[8], Lars Bolund[1,11], Xiuqing Zhang[1,6], Songgang Li[1,2,5], Huanming Yang[1,2,3] & Jian Wang[1,2,3]

Here we present the first diploid genome sequence of an Asian individual. The genome was sequenced to 36-fold average coverage using massively parallel sequencing technology. We aligned the short reads onto the NCBI human reference genome to 99.97% coverage, and guided by the reference genome, we used uniquely mapped reads to assemble a high-quality consensus sequence for 92% of the Asian individual's genome. We identified approximately 3 million single-nucleotide polymorphisms (SNPs) inside this region, of which 13.6% were not in the dbSNP database. Genotyping analysis showed that SNP identification had high accuracy and consistency, indicating the high sequence quality of this assembly. We also carried out heterozygote phasing and haplotype prediction against HapMap CHB and JPT haplotypes (Chinese and Japanese, respectively), sequence comparison with the two available individual genomes (J. D. Watson and J. C. Venter), and structural variation identification. These variations were considered for their potential biological impact. Our sequence data and analyses demonstrate the potential usefulness of next-generation sequencing technologies for personal genomics.

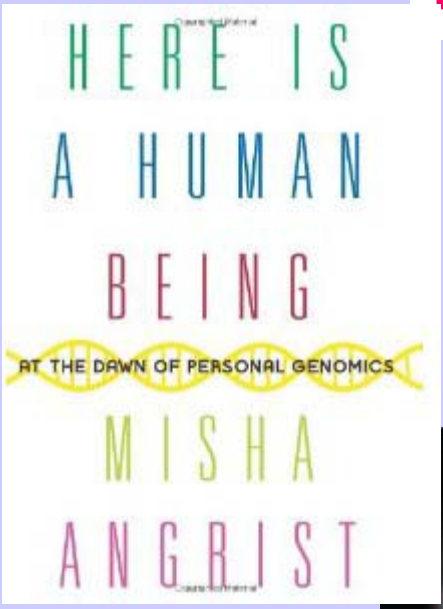
Genomic medicine
PPP: personalised, predictive, preventive

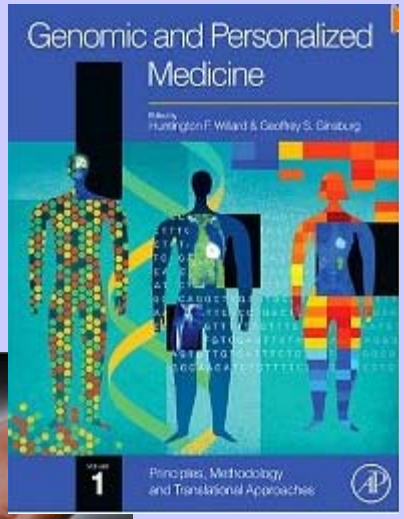
- Leroy Hood, 1992:

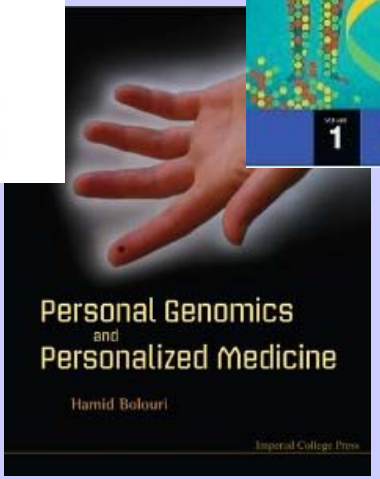
  "The genome project in the twenty-first century will have a profound impact on medicine, both for diagnosis and therapy … Perhaps the most important area of DNA diagnostics will be the identification of genes that predispose individuals to disease. However, many such diseases – cardiovascular, neurological, autoimmune – are polygenic; they are the result of the action of two or more genes. Human genetic mapping will permit the identification of specific predisposing genes and DNA diagnostics will facilitate their analysis in many different individuals … Perhaps in twenty years [he was writing in 1992] it will be possible to take DNA from newborns and analyze fifty or more genes for the allelic forms that can predispose the infant to many common diseases… For each defective gene there will be therapeutic regimens that will circumvent the limitations of the defective gene. Thus medicine will move from a reactive mode … to a preventive mode. Preventive medicine should enable most individuals to live a normal, healthy, and intellectually alert life without disease.



Has the genomics revolution finally arrived?







Direct-to-consumer personal genetic profiling

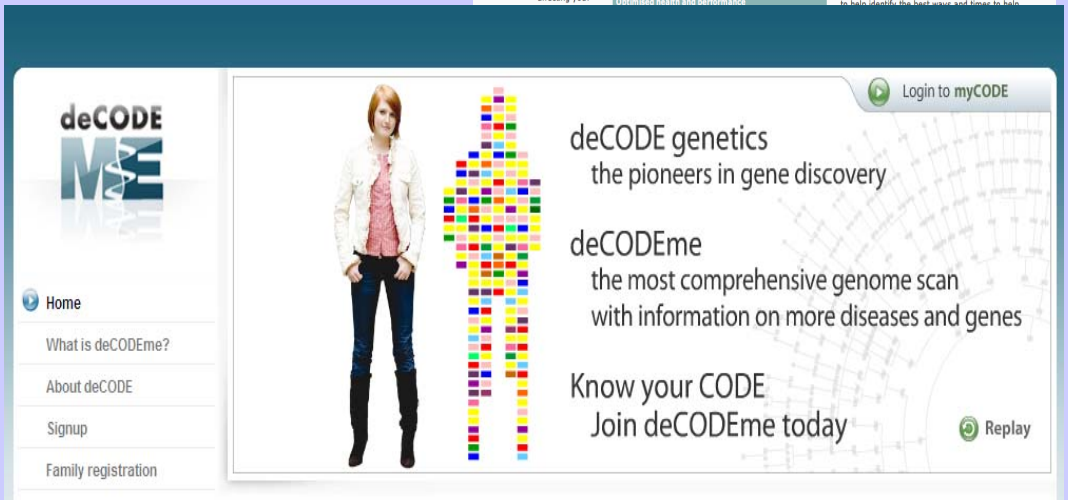
Company	Example product	Price	Details
23andMe	Health Edition	$429	"Find out if you carry inheritable markers for diseases such as breast cancer, cystic fibrosis, and Tay-Sachs…Learn your genetic risk for type 2 diabetes, Parkinson's disease, and other conditions."[420]
deCODEme	Complete Scan	$2000	"Calculate your genetic risk for 51 conditions…"[421]
Genetic Health	Premium Male	£825	"These are our most comprehensive test and includes all the other tests in our range… Evaluates the risk of prostate cancer as well as the risk for thrombosis, osteoporosis, metabolic imbalances of detoxification and chronic inflammation. It also evaluates the risk profile of the most common cardiovascular diseases…"[422]
Graceful Earth	Alzheimer's genome test	$280	"Check your future susceptibility BEFORE symptoms occur… Pre-emptive insight into one's genetic predisposition can empower and allow for pro-active prevention."[423]
Navigenics	Health Compass	Varies	"Knowing your genetic predispositions for important health conditions and medication reactions can help motivate you to take steps towards a healthier life. By gaining insight into these risks, you can plan for what's important."[424]

Knowing my very own future?

- Scan me
- Decode me
- The book of me
- Personalise me
- Kno(w)me
- Commodification of 'personal risk'
- Individualised biological prudence

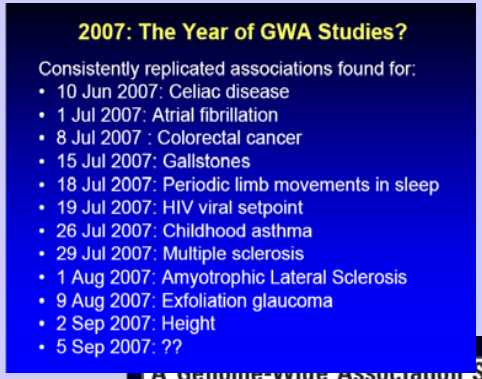
Our customers are saying...
"I thought how fascinating if I could know more about my future. I should know. I should be aware for myself. For my children. If there's something that I could prevent for the future, or live my life in a different way, why not learn? Why not help myself? And be knowledgeable in that information for my health and well-being."
~ Susan M.

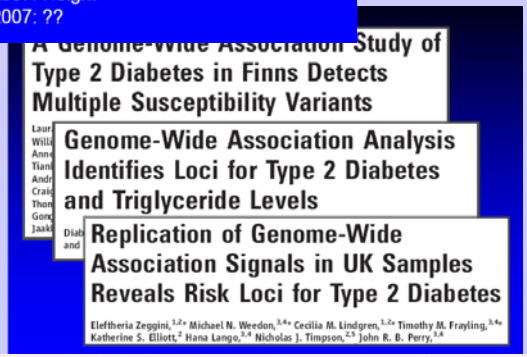
Knome
Know thyself.

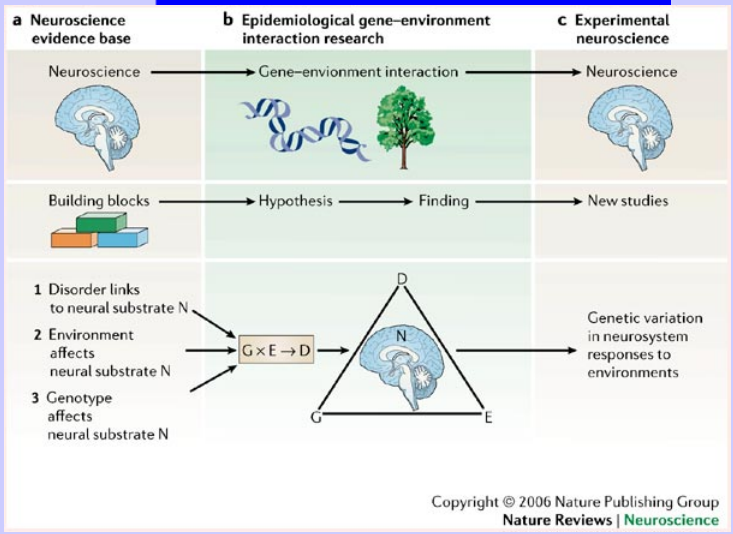


Susceptibility?

- From genetics to genomics
- The end of genetic determinism
- From 'biology is destiny' to knowing, managing and optimising biomedical futures
- From mutations – "the gene for" to SNPs for susceptibilities to common complex disorders, e.g. depression.
- Genome Wide Association Studies
  - The new logic, despite many flaws
    - (e.g. SNPs identified by GWAS account for less than 20% of familial heritability of breast cancer)
- From "Genes-R-Us to "G x E"
- Susceptibility as a form of life
    - With its own obligations and forms of responsibility







Gene–environment interactions in psychiatry: joining forces with neuroscience

Avshalom Caspi and Terrie E. Moffitt

Nature Reviews Neuroscience **7**, 583-590 (July 2006)

Biomedical patenting – a matter of life or death?
Michael Crichton, New York Times, February 2007

- "YOU, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real."

- **"Gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor. Gene patents slow the pace of medical advance on deadly diseases. And they raise costs exorbitantly: a test for breast cancer that could be done for $1,000 now costs $3,000."**

- "Why? Because the holder of the gene patent can charge whatever he wants, and does. Couldn't somebody make a cheaper test? Sure, but the patent holder blocks any competitor's test. He owns the gene. Nobody else can test for it. In fact, you can't even donate your own breast cancer gene to another scientist without permission. The gene may exist in your body, but it's now private property."

- Was Crichton right?

Personalised – from ‘we’ to ‘me’

BCM View of Personalized Medicine

- Best service
- Best quality based on evidence
- Individually tailored
- Backed by best science
- Genetically specific
- Fully Integrated
- Delivers best care and value
- Patient involvement

Baylor College of Medicine

BESTMINDS BESTMEDICINE

Phase I Development of a Custom GeneChip for the Baylor Clinic

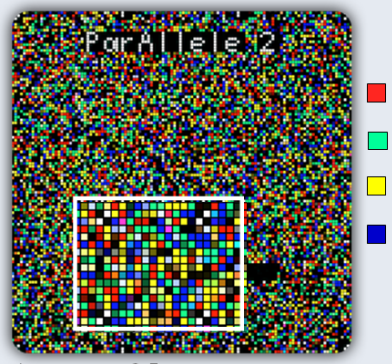
114 genes

161 diseases

1240 mutations

High impact mutations only

First step toward assays that carry out 100K – 1M gene tests



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BESTMINDS BESTMEDICINE

Johnson promises personalised NHS

Deborah Summers and agencies
guardian.co.uk, Sunday March 2 2008
Article history · Contact us

Alan Johnson, the health secretary. Photograph: Kirsty Wigglesworth/PA

The days of a "one-size-fits-all" NHS are over, Alan Johnson claimed today.

The health secretary used Labour's spring conference in Birmingham to set out the government's promise of a more personal health service

The Age of Personalized Medicine

A Service of PMC Personalized Medicine Coalition innovation.org

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Personalized Medicine

A new era of healthcare through:

Better medical outcomes.
Earlier interventions.
Improved diagnosis.

View of the Experts

Get to know the experts

21st Century Medicine: Personalized and Evidence-Based

Leading Policymakers, Scientists, Industry Executives Discuss Implementation of Evidence-Based, Personalized Medicine

View details from the PMC event

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PMC Personalized Medicine Coalition

THE CASE FOR PERSONALIZED MEDICINE

We present a case for personalized medicine, shedding light on its demonstrated benefits and limitations, and outlining a realistic scenario for its evolution.

Perils of PPP

- Reliability: Risk assessments vary between providers
- Validity: Even if assessments are reliable, they have little or no clinical relevance
- Results (risk information) difficult to interpret without much additional knowledge (e.g. population risk)
- Can't take account of factors other than genetic
- Evidence suggests people overestimate certainty and underestimate uncertainty
- In most cases there is little preventive action available apart from sensible lifestyle choices
- Consumerization: individualisation of risk and security
- Responsibilization: May increase belief in individual 'responsibility' for a future that cannot fully be known or managed

1 Janssens, Gwinn and Bradley *et al. (2008)* A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalize health interventions. *American Journal of Human Genetics* ***82(3): 593–9.***

Predictive: Screen and Intervene:

- "Earlier is (almost) always better…" – is it?
- Screening – who benefits?
  - Breast cancer?
  - Prostate cancer?
  - Psychopathy (children)?
  - Dementia (Mild Cognitive Impairment…)?

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News › Politics

NHS screening programme takes centre stage in Brown fightback

- PM launches drive to avert 200,000 deaths a year
- New attempt to regain initiative from Tories

David Hencke, Westminster correspondent
The Guardian, Monday 7 January 2008
Article history

Gordon Brown talks to people who have found work through a job centre in central London. Photograph: Lefteris Pitarakis/AP

The NHS is to launch a national screening programme to tackle some of Britain's biggest killer diseases, including heart attacks, strokes, diabetes and kidney failure, Gordon Brown will announce today. The programme, the first of its kind in the world, is expected to help prevent 200,000 deaths a year among the 6 million or more people who suffer from the targeted diseases, and heralds a switch in health priorities from curing illness to preventing it.
The announcement is intended to demonstrate the prime minister's commitment to making the "big

Published 24 September 2009, doi:10.1136/bmj.b3572
Cite this as: BMJ 2009;339:b3572

Editorials

Prostate specific antigen for detecting early prostate cancer

Evidence is inconclusive, so patient education and shared decision making are essential

The Washington Post

Article: Analysis: Mammograms Don't Cut Cancer Death Risk; Danish Researchers Find No Reliable Evidence in Major Studies to Support Medical Consensus

Article from: The Washington Post | Article date: October 19, 2001 | Author: Susan Okie |

Published online 19 October 2001 | Nature | doi:10.1038/news011025-5

News

Is screening for breast cancer with mammography justifiable?

Study questions whether mammography saves lives.

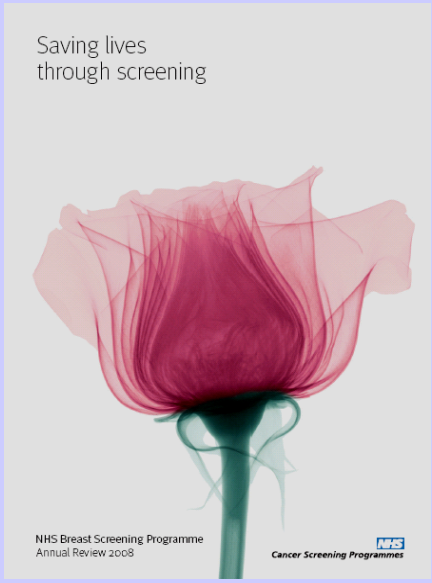
Mammography screening may not stand up to scrutiny. © SPL

Breast-cancer screening programmes may not save lives, according to a new examination of clinical trials. The controversial findings have led to calls for a re-evaluation of the routine monitoring procedure undergone by numerous women.

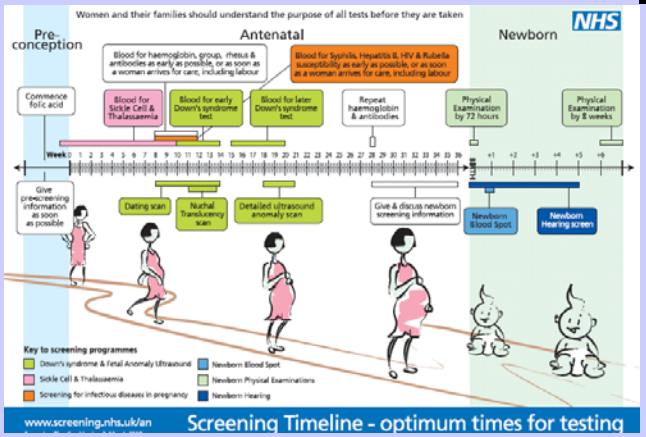
Mammography, X-ray breast imaging, is used in Europe and the United States to catch cancers early. "We've based a national screening programme on a set of results which do not stand up to scrutiny," says Richard Horton, editor of *The Lancet*, the medical journal that today publishes the peer-reviewed research.

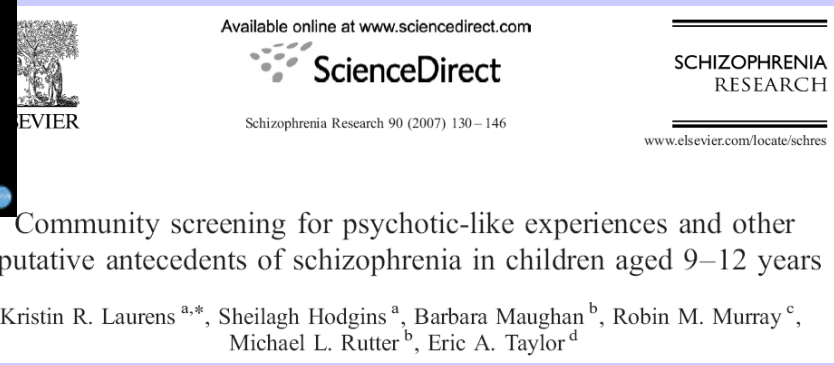
In January 2000, Ole Olsen and Peter Gotzsche of the Nordic Cochrane Centre in Copenhagen, Denmark first questioned whether regular screening of middle-aged women reduces the overall cancer death rate[1]. Their challenging re-analysis of large-scale mammography trials sparked public and medical controversy as some questioned the validity of the work.

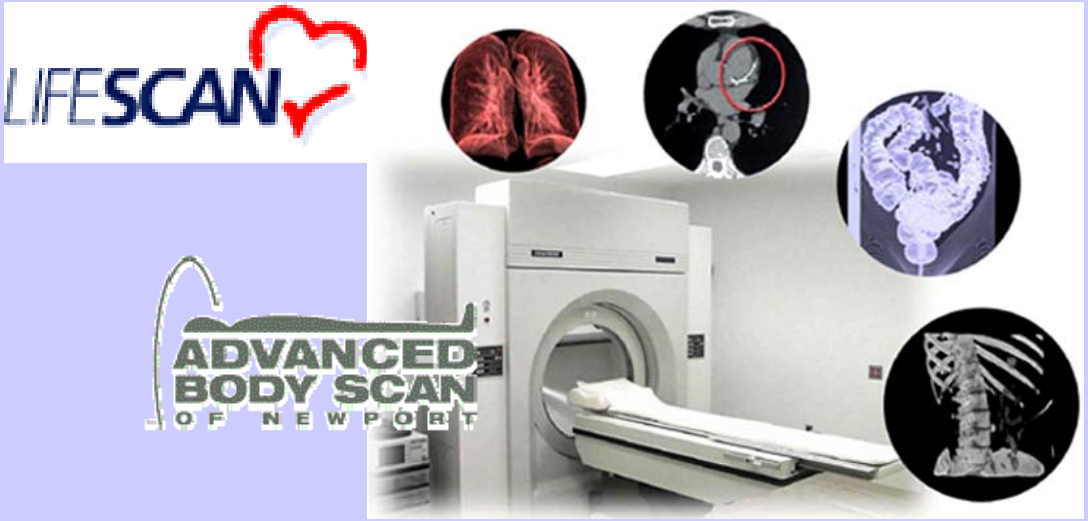
Now Olsen and Gotzsche have confirmed their earlier conclusions with



Screening – public value meets biovalue?







Biomarkers in psychiatry

THE LANCET Neurology

Review

The Lancet Neurology, Volume 7, Issue 8, Pages 704 - 714, August 2008
doi:10.1016/S1474-4422(08)70162-5 < Previous Article | Next Article >

Biomarkers for cognitive impairment and dementia in elderly people

Joshua A Sonnen MD [a], Kathleen S Montine PhD [a], Joseph F Quinn MD [b], Jeffrey A Kaye MD [b], John CS Breitner MD [c], Thomas J Montine MD [a b]

Summary

The threat of a looming pandemic of dementia in elderly people highlights the compelling need for the development and validation of biomarkers that can be used to identify pre-clinical and prodromal stages of disease in addition to fully symptomatic dementia. Although predictive risk factors and correlative neuroimaging measures will have important roles in these efforts, this Review describes recent progress in the discovery, validation, and standardisation of molecular biomarkers—small molecules and

NEWS

p5 Abstinence all the way: New US family planning chief slams premarital sex.

p7 Vietnam's winner: Menno de Jong fights for local scientists' rights.

p10 Acid test: Many with painful cluster headaches are self medicating with LSD.

Biomarkers trump behavior in mental illness diagnosis

Here's how doctors decide which mental or neurological disorder their troubled patients suffer from: they ask questions like, "Are you hearing voices?" and "Do you feel like people are out to get you?"

Not all that different from how they used to do it about 100 years ago.

New techniques are set to radically change that approach—and perhaps define new categories within each disease—relying more on changes in physiology than in behavior.

"Now we're at the opposite end of the spectrum where we can take an unbiased look," says Stephen Glatt, a psychiatric geneticist at the State University of New York in Syracuse.

Delusions, hallucinations, disorganized thinking and other psychotic symptoms can result from schizophrenia, Alzheimer disease, bipolar disorder, manic depression or dementia. Even diabetes and syphilis can induce forms of psychosis.

The answers to doctors' questions can help whittle down the categories somewhat, but it's far from a perfect science. Less than a third of individuals with these disorders respond to medications, most likely because they are being treated for the wrong one. The treatment for each illness can be drastically different, so pinning down the diagnosis is crucial.

Scientists are increasingly turning to biomarkers—such as genes or proteins in tissues, blood and body fluids—to distinguish between symptomatically indistinct illnesses.

"This is the holy grail of research," says Karoly Mirnics, associate professor of medical psychiatry at Vanderbilt University. Using techniques that have only become available in the past few years, scientists are looking at the brain, serum and spinal fluid and asking which combinations of genes or proteins might be expressed differently in these disorders.

The field is still far from ready for the clinic, but holds great promise: markers could allow for earlier treatment and a better prognosis, ultimately enabling scientists to intervene even before the full-blown disease strikes.

In one study published in November, researchers tested spinal fluid from patients at the first onset of schizophrenia. They found higher levels of a small protein derived from the protein VGF, known to be important for energy metabolism, and lower le… transthyretin compared wi… Post-mortem tissues of sc… showed… (*PLoS M…*

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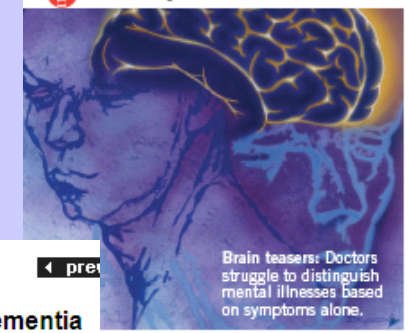

Brain teasers: Doctors struggle to distinguish mental illnesses based on symptoms alone.

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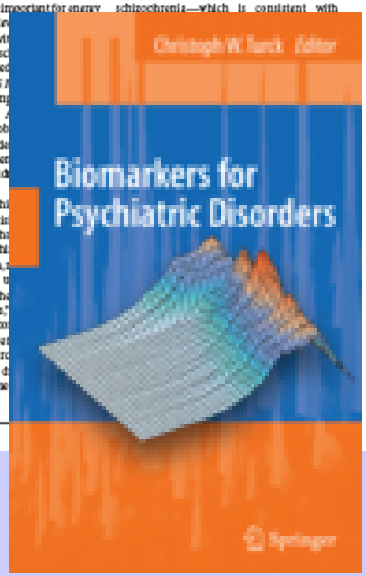

Biological Psychiatry
Official Journal of the Society of Biological Psychiatry

Volume 64, Issue 10, Pages 850-855 (15 November 2008)

Cerebrospinal Fluid Biomarkers in Parkinson's Disease with Dementia and Dementia with Lewy Bodies

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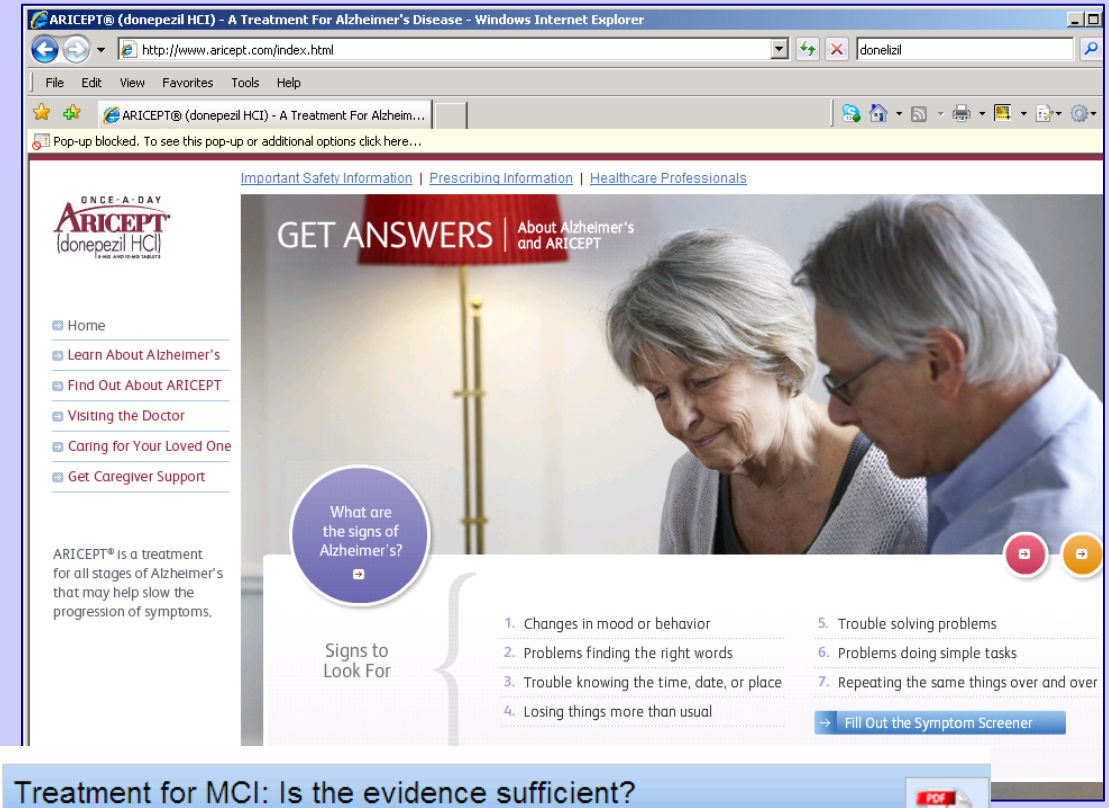
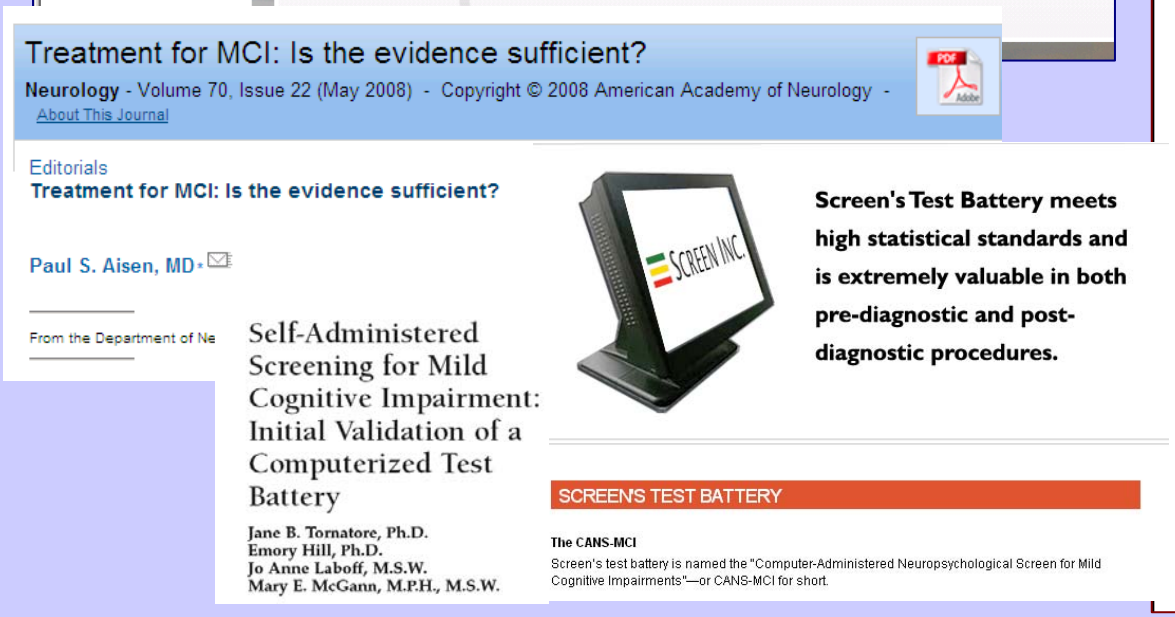
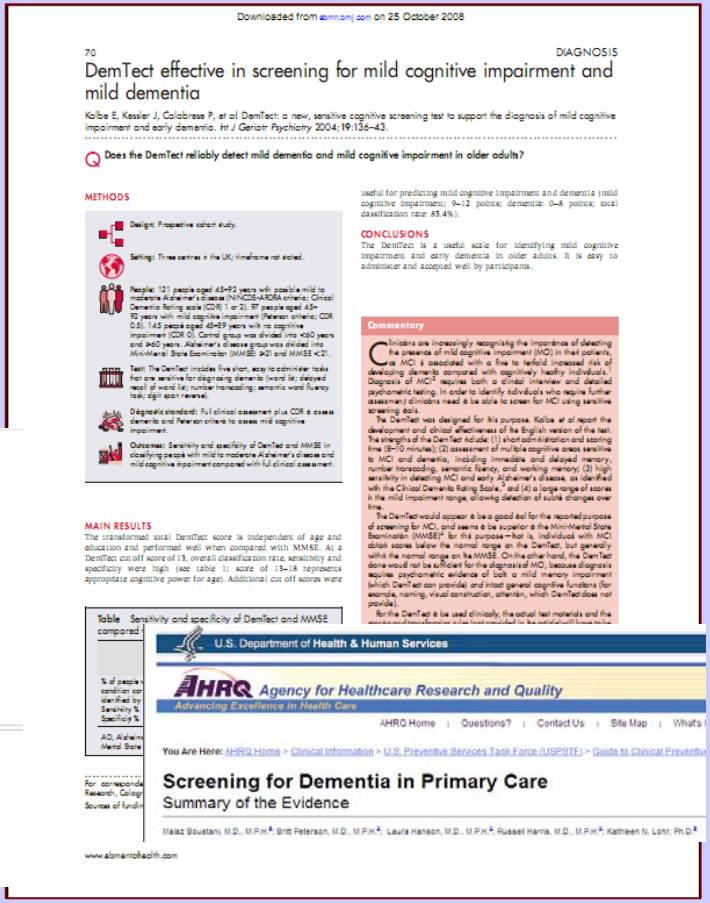
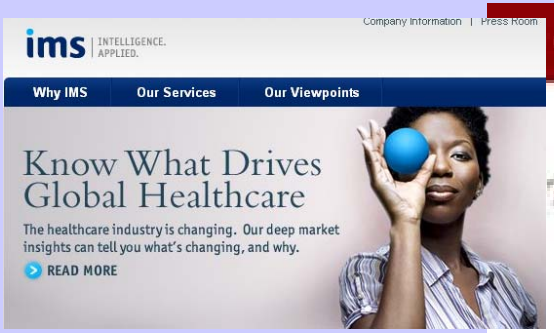
Mild Cognitive Impairment Aricept And Alzheimer's Disease

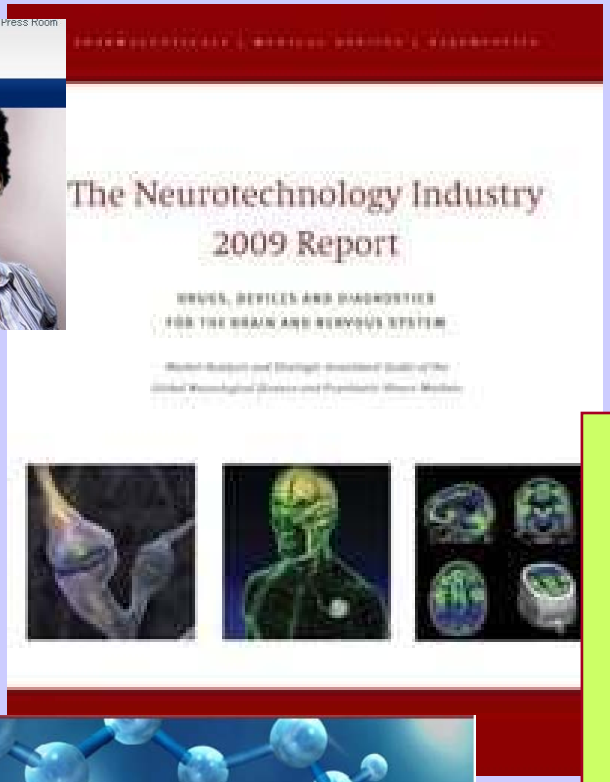


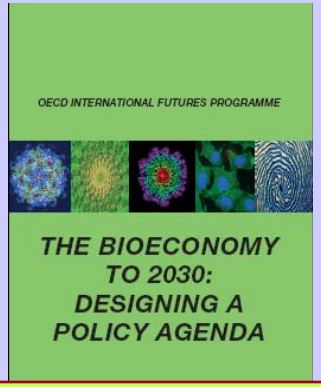


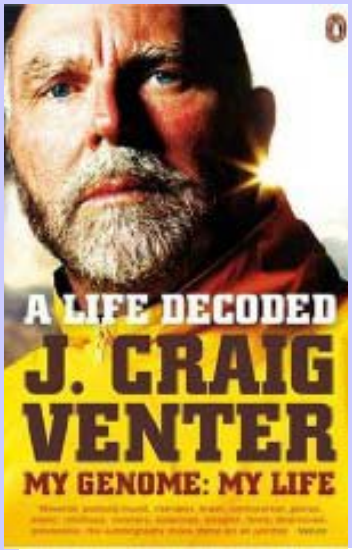


The economic drivers of biomedical technology

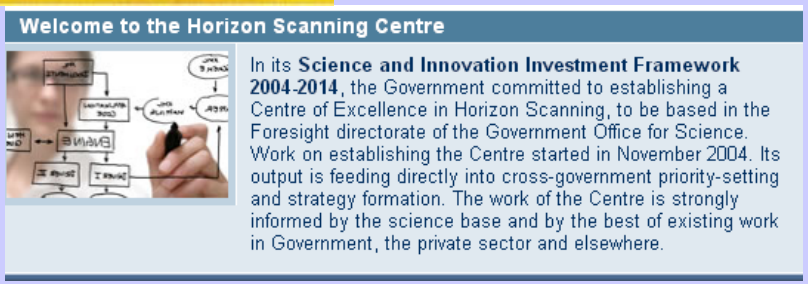


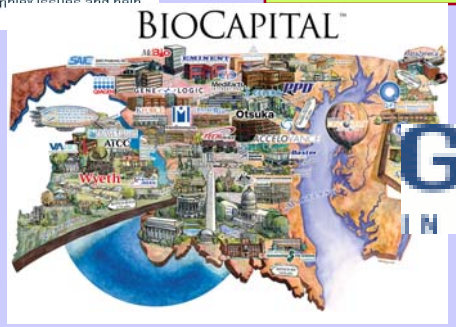






OECD (2006) 'the bioeconomy' is "that part of economic activities "which captures the latent value in biological processes and renewable bioresources to produce improved health and sustainable growth and development"





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Drivers and Implications of Biomedical Truth

- New alliance of state, market, university and science in search for biovalue.
- Truth of linked to health, or profit from health and market for health
- Biotechnology as a key national economic priority
- Path dependent theory of biomedical truth
- Biomedicine transforms how individuals think of their own health and disease
- Responsiblization - management of health as a personal responsibility
- Consumerization: Health and medicine as consumption goods
- De-socialization: unpooling of risks
- Illness not an occasional state but a constant hidden presence or potential within life itself

Thank you for your attention!

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